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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

Crop Insurance Regulations, Removal of a Miscellaneous Provision

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) is removing an outdated malting barley provision option that is no longer required in the administration of the Federal crop insurance program.

EFFECTIVE DATE: September 20, 2002.

FOR FURTHER INFORMATION CONTACT: Louise Narber, Insurance Management Specialist, Product Development Division, Federal Crop Insurance Corporation, 6501 Beacon Drive, Stop 0812, Room 421, Kansas City, MO, 64133-4676, telephone (816) 926-7730.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be exempt for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Paperwork Reduction Act of 1995

This rule does not contain information collection requirements that would require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments or the private sector. This

rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 13132

The rule will not have a substantial direct effect on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Nor does this rule impose substantial direct compliance costs on state and local governments. Therefore, consultation with the states is not required.

Regulatory Flexibility Act

This regulation will not have a significant economic impact on a substantial number of small entities. No additional work is required as a result of this action on the part of either the insured or the insurance companies. Additionally, the regulation does not require any greater action on the part of small entities than is required on the part of large entities. Therefore, this action is determined to be exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605), and no Regulatory Flexibility Analysis was prepared.

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372 which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. The administrative appeal provisions published at 7 CFR part 11 or 7 CFR

§ 400.169, as applicable, must be exhausted before any action for judicial review of any determination or action by FCIC may be brought.

Environmental Evaluation

This action is not expected to have a significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Background

FCIC has reviewed its regulations published at 7 CFR part 457 and determined that the provisions for malting barley published at § 457.103 are no longer applicable because the provisions currently in effect for malting barley are published at 7 CFR § 457.118.

Since the purpose of this rule is simply to remove the provisions that are no longer necessary in the administration of the Federal crop insurance program, this rule is considered a rule of agency practice or procedure. Therefore, under section 553(b) of the Administrative Procedures Act, this rule does not need to be published for notice and comment.

List of Subjects in 7 CFR Part 457

Crop Insurance, Malting barley.

Final Rule

Accordingly, under the authority of 7 U.S.C. 1506(l) and 1506(p), the Federal Crop Insurance Corporation hereby amends 7 CFR Chapter IV as follows:

PART 457—COMMON CROP INSURANCE REGULATIONS

1. The authority citation for part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

PART 457—[AMENDED]

2. In part 457, remove and reserve § 457.103.

Signed in Washington, DC, on August 15, 2002.

Ross J. Davidson, Jr.,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 02-21220 Filed 8-20-02; 8:45 am]

BILLING CODE 3410-08-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71****[Airspace Docket No. 02-ACE-3]****Establishment of Class E Airspace;
Caruthersville, MO****AGENCY:** Federal Aviation
Administration, DOT.**ACTION:** Direct final rule; confirmation
of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which establishes Class E airspace at Caruthersville, MO. The initial publication identified the airspace action as a modification of Class E airspace but, in fact, no Class E airspace area extending upward from 700 above the surface of the earth existed at Caruthersville, MO. The description of the established Class E airspace at Caruthersville, MO is unchanged from that of the initial publication.

EFFECTIVE DATE: 0901 UTC, October 3,
2002.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE-520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2524.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on April 18, 2002 (67 FR 19107). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on October 3, 2002. No adverse comments were received, and thus this document confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO, on August 5,
2002.

Paul J. Sheridan,

*Acting Manager, Air Traffic Division, Central
Region.*

[FR Doc. 02-21139 Filed 8-20-02; 8:45 am]

BILLING CODE 4910-13-M**DEPARTMENT OF ENERGY****Federal Energy Regulatory
Commission****18 CFR Part 381****[Docket No. RM02-15-000]****Annual Update of Filing Fees**

August 14, 2002.

AGENCY: Federal Energy Regulatory
Commission, DOE.**ACTION:** Final rule; annual update of
Commission filing fees.

SUMMARY: In accordance with 18 CFR 381.104, the Commission issues this update of its filing fees. This document provides the yearly update using data in the Commission's Management, Administrative, and Payroll System to calculate the new fees. The purpose of updating is to adjust the fees on the basis of the Commission's costs for Fiscal Year 2001.

EFFECTIVE DATE: September 20, 2002.

FOR FURTHER INFORMATION CONTACT: Troy Cole, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street, NE., Room 42-66, Washington, DC 20426, 202-502-6161.

SUPPLEMENTARY INFORMATION:

Document Availability: In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (<http://www.ferc.gov>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

From FERC's Home Page on the Internet, this information is available in both the Commission Issuance Posting System (CIPS) and the Records and Information Management System (RIMS).

—CIPS provides access to the texts of formal documents issued by the Commission since November 14, 1994.

—CIPS can be accessed using the CIPS link or the Energy Information Online icon. The full text of this document is available on CIPS in ASCII and WordPerfect 8.0 format for viewing, printing, and/or downloading.

—RIMS contains images of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed from FERC's Home Page using the RIMS link or the Energy Information Online icon. Descriptions of documents back to

November 16, 1981, are also available from RIMS-on-the-Web; requests for copies of these and other older documents should be submitted to the Public Reference Room.

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During normal business hours, documents can also be viewed and/or printed in FERC's Public Reference Room, where RIMS, CIPS, and the FERC Web site are available. User assistance is also available.

The Federal Energy Regulatory Commission (Commission) is issuing this document to update filing fees that the Commission assesses for specific services and benefits provided to identifiable beneficiaries. Pursuant to 18 CFR 381.104, the Commission is establishing updated fees on the basis of the Commission's Fiscal Year 2001 costs. The adjusted fees announced in this document are effective September 20, 2002. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this final rule is not a major rule within the meaning of section 251 of Subtitle E of Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. 804(2). The Commission is submitting this final rule to both houses of the United States Congress and to the Comptroller General of the United States.

The new fee schedule is as follows:

*Fees Applicable to the Natural Gas
Policy Act*

	Amount
1. Petitions for rate approval pursuant to 18 CFR 284.123(b)(2). (18 CFR 381.403)	\$ 9,090

Fees Applicable to General Activities

1. Petition for issuance of a declaratory order (except under Part I of the Federal Power Act). (18 CFR 381.302(a)) ..	18,260
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Amount in controversy	
\$0-9,999. (18 CFR 381.303(b))	100
\$10,000-29,999. (18 CFR 381.303(b))	600
\$30,000 or more. (18 CFR 381.303(a))	26,660
3. Review of a Department of Energy denial of adjustment:	
Amount in controversy	
\$0-9,999. (18 CFR 381.304(b))	100
\$10,000-29,999. (18 CFR 381.304(b))	600
\$30,000 or more. (18 CFR 381.304(a))	13,980
4. Written legal interpretations by the Office of General Counsel. (18 CFR 381.305(a))	5,240

Fees Applicable to Natural Gas Pipelines

1. Pipeline certificate applications pursuant to 18 CFR 284.224. (18 CFR 381.207(b)) 1,000

Fees Applicable to Cogenerators and Small Power Producers

1. Certification of qualifying status as a small power production facility. (18 CFR 381.505(a)) 15,700
2. Certification of qualifying status as a cogeneration facility. (18 CFR 381.505(a)) 17,770
3. Applications for exempt wholesale generator status. (18 CFR 381.801) 990

¹ This fee has not been changed.

List of Subjects in 18 CFR Part 381

Electric power plants, Electric utilities, Natural gas, Reporting and recordkeeping requirements.

Thomas R. Herlihy,
Executive Director and Chief Financial Officer.

In consideration of the foregoing, the Commission amends part 381, Chapter I, Title 18, Code of Federal Regulations, as set forth below.

PART 381—FEES

1. The authority citation for part 381 continues to read as follows:

Authority: 15 U.S.C. 717–717w; 16 U.S.C. 791–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; 49 U.S.C. 60502; 49 App. U.S.C. 1–85.

§ 381.302 [Amended]

2. In 381.302, paragraph (a) is amended by removing “\$16,530” and adding “\$18,260” in its place.

§ 381.303 [Amended]

3. In 381.303, paragraph (a) is amended by removing “\$24,140” and adding “\$26,660” in its place.

§ 381.304 [Amended]

4. In 381.304, paragraph (a) is amended by removing “\$12,650” and adding “\$13,980” in its place.

§ 381.305 [Amended]

5. In 381.305, paragraph (a) is amended by removing “\$4,740” and adding “\$5,240” in its place.

§ 381.403 [Amended]

6. Section 381.403 is amended by removing “\$8,230” and adding “\$9,090” in its place.

§ 381.505 [Amended]

7. In 381.505, paragraph (a) is amended by removing “\$14,220” and adding “\$15,700” in its place and by removing “\$16,090” and adding “\$17,770” in its place.

§ 381.801 [Amended]

8. Section 381.801 is amended by removing “\$970” and adding “\$990” in its place.

[FR Doc. 02–21157 Filed 8–20–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9013]

RIN 1545–AN64

Limitations on Passive Activity Losses and Credits—Treatment of Self-Charged Items of Income and Expense

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: These regulations provide guidance on the treatment of self-charged items of income and expense under section 469. The regulations recharacterize a percentage of certain portfolio income and expense as passive income and expense (self-charged items) when a taxpayer engages in a lending transaction with a partnership or an S corporation (passthrough entity) in which the taxpayer owns a direct or indirect interest and the loan proceeds are used in a passive activity. Similar rules apply to lending transactions between two identically owned passthrough entities. These final regulations affect taxpayers subject to the limitations on passive activity losses and credits.

DATES: *Effective Date:* These regulations are effective August 21, 2002.

Applicability Date: For dates of applicability of these regulations, see § 1.469–11 of these regulations.

FOR FURTHER INFORMATION CONTACT: Danielle M. Grimm at (202) 622–3070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1244. Responses to this collection of information are required to obtain the benefit of self-charged treatment of income and expense under section 469.

An agency may not conduct or sponsor, and a person is not required to

respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

The estimated annual burden per respondent varies from 5 minutes to 15 minutes, depending on individual circumstances, with an estimated average of 6 minutes.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Section 469(a)(1)(A) of the Internal Revenue Code (Code) provides that if aggregate losses from passive activities exceed aggregate income from passive activities for the taxable year, the excess losses are not allowable for that taxable year. Under section 469(e)(1), passive activity income does not include income from interest, dividends, annuities, and royalties not derived in the ordinary course of a trade or business. However, under the rules of § 1.163–8T, if borrowed funds are used in a passive activity, the interest expense is treated as a passive activity deduction. Consequently, in certain lending transactions, a taxpayer may have interest income that is characterized as portfolio income under section 469(e)(1) and interest expense that is characterized as a passive activity deduction under § 1.163–8T. The legislative history of section 469 indicates that this result is inappropriate because the items of interest income and expense are essentially “self-charged” and thus lack economic significance.

On April 5, 1991, the IRS published in the **Federal Register** a notice of proposed rulemaking (REG–209365–89 at 56 FR 14034) proposing amendments to 26 CFR part 1 under section 469 of the Code relating to the treatment of self-charged items of income and expense for purposes of applying the limitations on passive activity losses and passive activity credits.

A number of public comments were received and a public hearing was held on September 6, 1991. Given the significant period of time that had elapsed since the former comment period, additional comments were solicited in Notice 2001-47 (2001-36 I.R.B. 212). After consideration of all of the comments received, the proposed regulations are adopted, as revised by this Treasury decision.

Explanation of Revisions and Summary of Comments

The proposed regulations provide self-charged treatment for items of interest income and interest expense in lending transactions between a taxpayer and a passthrough entity in which the taxpayer holds a direct or qualifying indirect interest. Several commentators suggested that the regulations should also apply to lending transactions between related passthrough entities such as brother-sister entities in which the taxpayer owns interests because such transactions also may result in mismatched income and expense for purposes of section 469. In response to the suggestions, the self-charged rules are extended to identically owned passthrough entities. This extension is limited to identically owned entities because of concerns regarding the difficulty of identifying self-charged items in transactions between less closely related or unrelated entities.

Certain commentators requested the removal of the qualifying indirect interest rule in the proposed regulations. The qualifying indirect interest rule provides that a taxpayer must have at least a 10-percent indirect interest in a passthrough entity to qualify for self-charged treatment. Commentators noted that a taxpayer that owns less than a 10 percent interest nevertheless may receive large amounts of self-charged income and expense. This suggestion has been adopted. Accordingly, the regulations no longer contain the qualifying indirect interest rule.

Noting that Congress authorized the Secretary to identify other situations in which self-charged treatment is appropriate, several commentators suggested that self-charged treatment be extended to other transactions involving rental real estate activities, such as the payment of management fees and salaries. After publication of the proposed regulations, Congress considered the impact of section 469 on rental real estate transactions and enacted specific relief in section 469(c)(7) for certain real estate professionals for taxable years beginning after 1993. There was no indication in

the legislative history of section 469(c)(7) that Congress considered additional relief for real estate transactions necessary or desirable. Moreover, there is less justification for the complexity of a self-charged rule in this area after the enactment of section 469(c)(7) because that change substantially reduced the number of real estate transactions that would benefit from a self-charged rule. Accordingly, the regulations do not extend the self-charged treatment to other transactions involving rental real estate.

A number of comments suggested that the regulations clarify whether the self-charged rules apply to guaranteed payments to a partner for the use of capital. Section 1.469-2(e)(2)(ii) of the regulations treats these payments as interest income. Accordingly, the regulations clarify that lending transactions include guaranteed payments for the use of capital under section 707(c).

Some comments requested clarification on the types of interest eligible for self-charged treatment. The comments noted that the examples in the regulations may be interpreted as precluding certain types of interest because the introductory language states that the lending transactions described in the examples do not result in foregone interest (within the meaning of section 7872(e)(2)), original issue discount (within the meaning of section 1273), or total unstated interest (within the meaning of section 483(b)). Accordingly, the regulations clarify that the examples assume, solely for purposes of simplifying the presentation, that the lending transactions do not involve foregone interest, original issue discount, or total unstated interest.

A few comments responded to the notice of proposed rulemaking's solicitation for suggestions on the proper treatment of items recognized in different taxable years. One comment suggested the use of a suspense account. Under this suggestion, in the year in which the taxpayer identifies the corresponding item of self-charged income or expense, that item would be netted against the self-charged item in the suspense account. Another comment suggested that where the recognition of passive interest expense precedes the recognition of passive income, the taxpayer could elect to treat the income as passive when ultimately recognized. Another suggestion was to allow the taxpayer to recharacterize interest income or expense equal to the amount calculated on a cumulative basis. The commentators recognize that to

implement the above methods would require more complex regulations.

After consideration of these comments, the final regulations adopt the rule of the proposed regulations that the self-charged rules apply only to self-charged items recognized in the same taxable year. This rule is consistent with the legislative history and avoids the complexity of the other suggested methods. For similar reasons, comments suggesting special rules for capitalized expenses are not adopted.

Certain commentators requested that the regulations be extended to apply to transactions between taxpayers and their trusts, estates, REMICs and housing cooperatives. The regulations address the transactions identified by Congress involving S corporations and partnerships (including entities classified as partnerships for federal tax purposes). Application of the self-charged rules to other types of entities would require a significant expansion of the scope of these regulations to address broader issues concerning the manner in which section 469 applies to those entities.

The applicability date of the final regulations is consistent with the applicability date as proposed. However, certain clarifications have been made to the transition rule. In the transition period, a taxpayer may use any reasonable method to offset items of interest income and interest expense from lending transactions.

Effective Date

These regulations are applicable for taxable years beginning after December 31, 1986. However, for taxable years beginning before June 4, 1991, a taxpayer that owns an interest in a passthrough entity is not required to apply these provisions and may use any reasonable method to offset items of interest income and interest expense from lending transactions between the passthrough entity and its owners or between certain passthrough entities. Items from nonlending transactions cannot be offset under the self-charged rules.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12886. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required.

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Danielle M. Grimm, Office of the Associate Chief Counsel (Passthroughs and Special Industries), Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income Taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *
Section 1.469-7 also issued under 26 U.S.C. 469(l). * * *

Par. 2. Section 1.469-0 is amended by:

1. Revising the entry for § 1.469-7.
2. Adding entries for § 1.469-7(a) through (h).
3. Revising the entries for § 1.469-11(c)(1) and (c)(1)(i).
4. Adding an entry for § 1.469-11, paragraph (c)(1)(iii).

The additions and revisions read as follows:

§ 1.469-0 Table of contents.

* * * * *

§ 1.469-7 Treatment of self-charged items of interest income and deduction.

- (a) In general.
 - (1) Applicability and effect of rules.
 - (2) Priority of rules in this section.
- (b) Definitions.
 - (1) Passthrough entity.
 - (2) Taxpayer's share.
 - (3) Taxpayer's indirect interest.
 - (4) Entity taxable year.
 - (5) Deductions for a taxable year.
 - (c) Taxpayer loans to passthrough entity.
 - (1) Applicability.
 - (2) General rule.

- (3) Applicable percentage.
- (d) Passthrough entity loans to taxpayer.
 - (1) Applicability.
 - (2) General rule.
 - (3) Applicable percentage.
- (e) Identically-owned passthrough entities.
 - (1) Applicability.
 - (2) General rule.
 - (3) Example.
- (f) Identification of properly allocable deductions.
 - (1) In general.
 - (2) Form of election.
 - (3) Period for which election applies.
 - (4) Revocation.
 - (h) Examples.

§ 1.469-11 Effective date and transition rules.

- * * * * *
- (c) * * *
- (1) Application of certain income recharacterization rules and self-charged rules.
 - (i) Certain recharacterization rules inapplicable in 1987.

* * * * *
 - (iii) Self-charged rules.

* * * * *

Par. 3. Section 1.469-7 is amended by:

- (1) Revising the section heading.
 - (2) Adding paragraphs (a) through (h).
- The revision and additions read as follows:

§ 1.469-7 Treatment of self-charged items of interest income and deduction.

(a) *In general*—(1) *Applicability and effect of rules.* This section sets forth rules that apply, for purposes of section 469 and the regulations thereunder, in the case of a lending transaction (including guaranteed payments for the use of capital under section 707(c)) between a taxpayer and a passthrough entity in which the taxpayer owns a direct or indirect interest, or between certain passthrough entities. The rules apply only to items of interest income and interest expense that are recognized in the same taxable year. The rules—

- (i) Treat certain interest income resulting from these lending transactions as passive activity gross income;
 - (ii) Treat certain deductions for interest expense that is properly allocable to the interest income as passive activity deductions; and
 - (iii) Allocate the passive activity gross income and passive activity deductions resulting from this treatment among the taxpayer's activities.
- (2) *Priority of rules in this section.* The character of amounts treated under the rules of this section as passive activity gross income and passive activity deductions and the activities to which

these amounts are allocated are determined under the rules of this section and not under the rules of §§ 1.163-8T, 1.469-2(c) and (d), and 1.469-2T(c) and (d).

(b) *Definitions.* The following definitions set forth the meaning of certain terms for purposes of this section:

(1) *Passthrough entity.* The term *passthrough entity* means a partnership or an S corporation.

(2) *Taxpayer's share.* A *taxpayer's share* of an item of income or deduction of a passthrough entity is the amount treated as an item of income or deduction of the taxpayer for the taxable year under section 702 (relating to the treatment of distributive shares of partnership items as items of partners) or section 1366 (relating to the treatment of pro rata shares of S corporation items as items of shareholders).

(3) *Taxpayer's indirect interest.* The taxpayer has an indirect interest in an entity if the interest is held through one or more passthrough entities.

(4) *Entity taxable year.* In applying this section for a taxable year of a taxpayer, the term *entity taxable year* means the taxable year of the passthrough entity for which the entity reports items that are taken into account under section 702 or section 1366 for the taxpayer's taxable year.

(5) *Deductions for a taxable year.* The term *deductions for a taxable year* means deductions that would be allowable for the taxable year if the taxpayer's taxable income for all taxable years were determined without regard to sections 163(d), 170(b), 469, 613A(d), and 1211.

(c) *Taxpayer loans to passthrough entity*—(1) *Applicability.* Except as provided in paragraph (g) of this section, this paragraph (c) applies with respect to a taxpayer's interest in a passthrough entity (borrowing entity) for a taxable year if—

(i) The borrowing entity has deductions for the entity taxable year for interest charged to the borrowing entity by persons that own direct or indirect interests in the borrowing entity at any time during the entity taxable year (the borrowing entity's self-charged interest deductions);

(ii) The taxpayer owns a direct or an indirect interest in the borrowing entity at any time during the entity taxable year and has gross income for the taxable year from interest charged to the borrowing entity by the taxpayer or a passthrough entity through which the taxpayer holds an interest in the borrowing entity (the taxpayer's income from interest charged to the borrowing entity); and

(iii) The taxpayer's share of the borrowing entity's self-charged interest deductions includes passive activity deductions.

(2) *General rule.* If any of the borrowing entity's self-charged interest deductions are allocable to an activity for a taxable year in which this paragraph (c) applies, the passive activity gross income and passive activity deductions from that activity are determined under the following rules—

(i) The applicable percentage of each item of the taxpayer's income for the taxable year from interest charged to the borrowing entity is treated as passive activity gross income from the activity; and

(ii) The applicable percentage of each deduction for the taxable year for interest expense that is properly allocable (within the meaning of paragraph (f) of this section) to the taxpayer's income from the interest charged to the borrowing entity is treated as a passive activity deduction from the activity.

(3) *Applicable percentage.* In applying this paragraph (c) with respect to a taxpayer's interest in a borrowing entity, the applicable percentage is separately determined for each of the taxpayer's activities. The percentage applicable to an activity for a taxable year is obtained by dividing—

(i) The taxpayer's share for the taxable year of the borrowing entity's self-charged interest deductions that are treated as passive activity deductions from the activity by

(ii) The greater of—

(A) The taxpayer's share for the taxable year of the borrowing entity's aggregate self-charged interest deductions for all activities (regardless of whether these deductions are treated as passive activity deductions); or

(B) The taxpayer's aggregate income for the taxable year from interest charged to the borrowing entity for all activities of the borrowing entity.

(d) *Passthrough entity loans to taxpayer—(1) Applicability.* Except as provided in paragraph (g) of this section, this paragraph (d) applies with respect to a taxpayer's interest in a passthrough entity (lending entity) for a taxable year if—

(i) The lending entity has gross income for the entity taxable year from interest charged by the lending entity to persons that own direct or indirect interests in the lending entity at any time during the entity taxable year (the lending entity's self-charged interest income);

(ii) The taxpayer owns a direct or an indirect interest in the lending entity at

any time during the entity taxable year and has deductions for the taxable year for interest charged by the lending entity to the taxpayer or a passthrough entity through which the taxpayer holds an interest in the lending entity (the taxpayer's deductions for interest charged by the lending entity); and

(iii) The taxpayer's deductions for interest charged by the lending entity include passive activity deductions.

(2) *General rule.* If any of the taxpayer's deductions for interest charged by the lending entity are allocable to an activity for a taxable year in which this paragraph (d) applies, the passive activity gross income and passive activity deductions from that activity are determined under the following rules—

(i) The applicable percentage of the taxpayer's share for the taxable year of each item of the lending entity's self-charged interest income is treated as passive activity gross income from the activity.

(ii) The applicable percentage of the taxpayer's share for the taxable year of each deduction for interest expense that is properly allocable (within the meaning of paragraph (f) of this section) to the lending entity's self-charged interest income is treated as a passive activity deduction from the activity.

(3) *Applicable percentage.* In applying this paragraph (d) with respect to a taxpayer's interest in a lending entity, the applicable percentage is separately determined for each of the taxpayer's activities. The percentage applicable to an activity for a taxable year is obtained by dividing—

(i) The taxpayer's deductions for the taxable year for interest charged by the lending entity, to the extent treated as passive activity deductions from the activity; by

(ii) The greater of—

(A) The taxpayer's aggregate deductions for all activities for the taxable year for interest charged by the lending entity (regardless of whether these deductions are treated as passive activity deductions); or

(B) The taxpayer's aggregate share for the taxable year of the lending entity's self-charged interest income for all activities of the lending entity.

(e) *Identically-owned passthrough entities—(1) Applicability.* Except as provided in paragraph (g) of this section, this paragraph (e) applies with respect to lending transactions between passthrough entities if each owner of the borrowing entity has the same proportionate ownership interest in the lending entity.

(2) *General rule.* To the extent an owner shares in interest income from a

loan between passthrough entities described in paragraph (e)(1) of this section, the owner is treated as having made the loan to the borrowing passthrough entity and paragraph (c) of this section applies to determine the applicable percentage of portfolio income of properly allocable interest expense that is recharacterized as passive.

(3) *Example.* The following example illustrates the application of this paragraph (e):

Example. (i) A and B, both calendar year taxpayers, each own a 50-percent interest in the capital and profits of partnerships RS and XY, both calendar year partnerships. Under the partnership agreements of RS and XY, A and B are each entitled to a 50-percent distributive share of each partnership's income, gain, loss, deduction, or credit. RS makes a \$20,000 loan to XY and XY pays RS \$2,000 of interest for the taxable year. A's distributive share of interest income attributable to this loan is \$1,000 (50 percent \times \$2,000). XY uses all of the proceeds received from RS as a passive activity. A's distributive share of interest expense attributable to the loan is \$1,000 (50 percent \times \$2,000).

(ii) This paragraph (e) applies in determining A's passive activity gross income because RS and XY are identically-owned passthrough entities as described in paragraph (e)(1) of this section. Under paragraph (e)(2) of this section, the RS-to-XY loan is treated as if A made the loan to XY. Therefore, A must apply paragraph (c) of this section to determine the applicable percentage of portfolio income that is recharacterized as passive income.

(iii) Paragraph (c) of this section applies in determining A's passive activity gross income because: XY has deductions for interest charged to XY by RS for the taxable year (XY's self-charged interest deductions); A owns an interest in XY during XY's taxable year and has gross income for the taxable year from interest charged to XY by RS; and A's share of XY's self-charged interest deductions includes passive activity deductions. See paragraph (c)(1) of this section.

(iv) Under paragraph (c)(2)(i) of this section, the applicable percentage of A's interest income is recharacterized as passive activity gross income from the activity. Paragraph (c)(3) of this section provides that the applicable percentage is obtained by dividing A's share for the taxable year of XY's self-charged interest deductions that are treated as passive activity deductions from the activity (\$1,000) by the greater of A's share for the taxable year of XY's self-charged interest deductions (\$1,000), or A's income for the year from interest charged to XY (\$1,000). Thus, A's applicable percentage is 100 percent (\$1,000/\$1,000), and \$1,000 (100 percent \times \$1,000) of A's income from interest charged to XY is treated as passive activity gross income from the passive activity.

(f) *Identification of properly allocable deductions.* For purposes of this section, interest expense is properly allocable to

an item of interest income if the interest expense is allocated under § 1.163-8T to an expenditure that—

(1) Is properly chargeable to capital account with respect to the investment producing the item of interest income; or

(2) May reasonably be taken into account as a cost of producing the item of interest income.

(g) *Election to avoid application of the rules of this section*—(1) *In general.* Paragraphs (c), (d) and (e) of this section shall not apply with respect to any taxpayer's interest in a passthrough entity for a taxable year if the passthrough entity has made, under this paragraph (g), an election that applies to the entity's taxable year.

(2) *Form of election.* A passthrough entity makes an election under this paragraph (g) by attaching to its return (or amended return) a written statement that includes the name, address, and taxpayer identification number of the passthrough entity and a declaration that an election is being made under this paragraph (g).

(3) *Period for which election applies.* An election under this paragraph (g) made with a return (or amended return) for a taxable year applies to that taxable year and all subsequent taxable years that end before the date on which the election is revoked.

(4) *Revocation.* An election under this paragraph (g) may be revoked only with the consent of the Commissioner.

(h) *Examples.* The following examples illustrate the principles of this section. The examples assume for purposes of simplifying the presentation, that the lending transactions described do not result in foregone interest (within the meaning of section 7872(e)(2)), original issue discount (within the meaning of section 1273), or total unstated interest (within the meaning of section 483(b)).

Example 1. (i) A and B, two calendar year individuals, each own 50-percent interests in the capital, profits and losses of AB, a calendar year partnership. AB is engaged in a single rental activity within the meaning of § 1.469-1T(e)(3). AB borrows \$50,000 from A and uses the loan proceeds in the rental activity. AB pays \$5,000 of interest to A for the taxable year. A and B each incur \$2,500 of interest expense as their distributive share of AB's interest expense.

(ii) AB has self-charged interest deductions for the taxable year (i.e., the deductions for interest charged to AB by A); A owns a direct interest in AB during AB's taxable year and has income for A's taxable year from interest charged to AB; and A's share of AB's self-charged interest deductions includes passive activity deductions. Accordingly, paragraph (c) of this section applies in determining A's passive activity gross income. See paragraph (c)(1) of this section.

(iii) Under paragraph (c)(2)(i) of this section, the applicable percentage of A's interest income is recharacterized as passive activity gross income from AB's rental activity. Paragraph (c)(3) of this section provides that the applicable percentage is obtained by dividing A's share for the taxable year of AB's self-charged interest deductions that are treated as passive activity deductions from the activity (\$2,500) by the greater of A's share for the taxable year of AB's self-charged interest deductions (\$2,500), or A's income for the taxable year from interest charged to AB (\$5,000). Thus, A's applicable percentage is 50 percent (\$2,500/\$5,000), and \$2,500 (50 percent \times \$5,000) of A's income from interest charged to AB is treated as passive activity gross income from the passive activity A conducts through AB.

(iv) Because B does not have any gross income for the year from interest charged to AB, this section does not apply to B. See paragraph (c)(1)(ii) of this section.

Example 2. (i) C and D, two calendar year taxpayers, each own 50-percent interests in the capital and profits of CD, a calendar year partnership. CD is engaged in a single rental activity, within the meaning of § 1.469-1T(e)(3). C obtains a \$10,000 loan from a third-party lender, and pays the lender \$900 in interest for the taxable year. C lends the \$10,000 to CD, and receives \$1,000 of interest income from CD for the taxable year. D lends \$20,000 to CD and receives \$2,000 of interest income from CD for the taxable year. CD uses all of the proceeds in the rental activity. C and D are each allocated \$1,500 (50 percent \times \$3,000) of interest expense as their distributive share of CD's interest expense for the taxable year.

(ii) CD has self-charged interest deductions for the taxable year (i.e., deductions for interest charged to CD by C and D); C and D each own direct interests in CD during CD's taxable year and have gross income for the taxable year from interest charged to CD; and both C's and D's shares of CD's self-charged interest deductions include passive activity deductions. Accordingly, paragraph (c) of this section applies in determining C's and D's passive activity gross income. See paragraph (c)(1) of this section.

(iii) Under paragraph (c)(2)(i) of this section, the applicable percentage of each partner's interest income is recharacterized as passive activity gross income from CD's rental activity. Paragraph (c)(3) of this section provides that C's applicable percentage is obtained by dividing C's share for the taxable year of CD's self-charged interest deductions that are treated as passive activity deductions from the activity (\$1,500) by the greater of C's share for the taxable year of CD's self-charged interest deductions (\$1,500), or C's income for the taxable year from interest charged to CD (\$1,000). Thus, C's applicable percentage is 100 percent (\$1,500/\$1,500), and all of C's income from interest charged to CD (\$1,000) is treated as passive activity gross income from the passive activity C conducts through CD. Similarly, D's applicable percentage is obtained by dividing D's share for the taxable year of CD's self-charged interest deductions that are treated as passive activity deductions from the activity (\$1,500) by the greater of D's share for the taxable year of CD's self-charged

interest deductions (\$1,500), or D's income for the taxable year from interest charged to CD (\$2,000). Thus, D's applicable percentage is 75 percent (\$1,500/\$2,000), and \$1,500 (75 percent \times \$2,000) of D's income from interest charged to CD is treated as passive activity gross income from the rental activity.

(iv) The \$900 of interest expense that C pays to the third-party lender is allocated under § 1.163-8T(c)(1) to an expenditure that is properly chargeable to capital account with respect to the loan to CD. Thus, the expense is properly allocable to the interest income C receives from CD (see paragraph (f) of this section). Under paragraph (c)(2)(ii) of this section, the applicable percentage of C's deductions for the taxable year for interest expense that is properly allocable to C's income from interest charged to CD is recharacterized as a passive activity deduction from CD's rental activity. Accordingly, all of C's \$900 interest deduction is treated as a passive activity deduction from the rental activity.

Example 3. (i) E and F, calendar year taxpayers, each own 50 percent of the stock of X, a calendar year S corporation. E borrows \$30,000 from X, and pays X \$3,000 of interest for the taxable year. E uses \$15,000 of the loan proceeds to make a personal expenditure (as defined in § 1.163-8T(b)(5)), and uses \$15,000 of loan proceeds to purchase a trade or business activity in which E does not materially participate (within the meaning of § 1.469-5T) for the taxable year. E and F each receive \$1,500 as their pro rata share of X's interest income from the loan for the taxable year.

(ii) X has gross income for X's taxable year from interest charged to E (X's self-charged interest income); E owns a direct interest in X during X's taxable year and has deductions for the taxable year for interest charged by X; and E's deductions for interest charged by X include passive activity deductions.

Accordingly, paragraph (d) of this section applies in determining E's passive activity gross income. See paragraph (d)(1) of this section.

(iii) Under the rules in paragraph (d)(2)(i) of this section, the applicable percentage of E's share of X's self-charged interest income is recharacterized as passive activity gross income from the activity. Paragraph (d)(3) of this section provides that the applicable percentage is obtained by dividing E's deductions for the taxable year for interest charged by X, to the extent treated as passive activity deductions from the activity (\$1,500), by the greater of E's deductions for the taxable year for interest charged by X, regardless of whether those deductions are treated as passive activity deductions (\$3,000), or E's share for the taxable year of X's self-charged interest income (\$1,500). Thus, E's applicable percentage is 50 percent (\$1,500/\$3,000), and \$750 (50 percent \times \$1,500) of E's share of X's self-charged interest income is treated as passive activity gross income.

(iv) Because F does not have any deductions for the taxable year for interest charged by X, this section does not apply to F. See paragraph (d)(1)(ii) of this section.

Example 4. (i) This *Example 4* illustrates the application of this section to a partner

that has a different taxable year from the partnership. The facts are the same as in *Example 1* except as follows: Partnership AB has properly adopted a fiscal year ending June 30 for federal tax purposes; AB borrows the \$50,000 from A on October 1, 1990; and under the terms of the loan, AB must pay A \$5,000 in interest annually, in quarterly installments, for a term of 2 years.

(ii) For A's taxable years from 1990 through 1993 and AB's corresponding entity taxable years (as defined in paragraph (b)(4) of this section) A's interest income and AB's interest deductions from the loan are as follows:

	A's interest income	AB's interest deductions
1990	\$1,250	0
1991	5,000	\$3,750
1992	3,750	5,000
1993	0	1,250

(iii) For A's taxable year ending December 31, 1990, the corresponding entity taxable year is AB's taxable year ending June 30, 1990. Because AB does not have any deductions for the entity taxable year for interest charged to AB by A, paragraph (c) of this section does not apply in determining A's passive activity gross income for 1990 (see paragraph (c)(1)(i) of this section). Accordingly, A reports \$1,250 of portfolio income on A's 1990 income tax return.

(iv) For A's taxable year ending December 31, 1991, the corresponding entity taxable year ends on June 30, 1991. AB has \$3,750 of deductions for the entity taxable year for interest charged to AB by A (AB's self-charged interest deductions); A owns a direct interest in AB during the entity taxable year and has \$5,000 of interest income for A's taxable year from interest charged to AB; and A's share of AB's self-charged interest deductions includes passive activity deductions. Accordingly, paragraph (c) of this section applies in determining A's passive activity gross income.

(v) Under paragraph (c)(2)(i) of this section, the applicable percentage of A's 1991 interest income is recharacterized as passive activity gross income from the activity. Paragraph (c)(3) of this section provides that the applicable percentage is obtained by dividing A's share for A's 1991 taxable year of AB's self-charged interest deductions that are treated as passive activity deductions from the activity (50 percent \times \$3,750 = \$1,875) by the greater of A's share for A's taxable year of AB's self-charged interest deductions (\$1,875), or A's income for A's taxable year from interest charged to AB (\$5,000). Thus, A's applicable percentage is 37.5 percent (\$1,875/\$5,000), and \$1,875 (37.5 percent \times \$5,000) of A's income from interest charged to AB is treated as passive activity gross income from the passive activity A conducts through AB.

(vi) For A's taxable year ending December 31, 1992, the corresponding entity taxable year ends on June 30, 1992. AB has \$5,000 of deductions for the entity taxable year for interest charged to AB by A (AB's self-charged interest deductions); A owns a direct interest in AB during the entity taxable year

and has \$3,750 of gross income for A's taxable year from interest charged to AB; and A's share of AB's self-charged interest deductions includes passive activity deductions. Accordingly, paragraph (c) of this section applies in determining A's passive activity gross income.

(vii) The applicable percentage for 1992 is obtained by dividing A's share for A's 1992 taxable year of AB's self-charged interest deductions that are treated as passive activity deductions from the activity (\$2,500) by the greater of A's share for A's taxable year of AB's self-charged interest deductions (\$2,500), or A's income for A's taxable year from interest charged to AB (\$3,750). Thus, A's applicable percentage is 66 $\frac{2}{3}$ percent (\$2,500/\$3,750), and \$2,500 (66 $\frac{2}{3}$ percent \times \$3,750) of A's income from interest charged to AB is treated as passive activity gross income from the passive activity A conducts through AB.

(viii) Paragraph (c) of this section does not apply in determining A's passive activity gross income for the taxable year ending December 31, 1993, because A has no gross income for the taxable year from interest charged to AB (see paragraph (c)(1)(ii) of this section). A's share of AB's self-charged interest deductions for the entity taxable year ending June 30, 1993 (\$625) is taken into account as a passive activity deduction on A's 1993 income tax return.

(ix) Because B does not have any gross income from interest charged to AB for any of the taxable years, this section does not apply to B. See paragraph (c)(1)(ii) of this section.

Example 5. (i) This *Example 5* illustrates the application of the rules of this section in the case of a taxpayer who has an indirect interest in a partnership. G, a calendar year taxpayer, is an 80-percent partner in partnership UTP. UTP owns a 25-percent interest in the capital and profits of partnership LTP. UTP and LTP are both calendar year partnerships. The partners of LTP conduct a single passive activity through LTP. UTP obtains a \$10,000 loan from a bank, and pays the bank \$1,000 of interest per year. G's distributive share of the interest paid to the bank is \$800 (80 percent \times \$1,000). UTP uses the \$10,000 debt proceeds and another \$10,000 of cash to make a loan to LTP, and LTP pays UTP \$2,000 of interest for the taxable year. G's distributive share of interest income attributable to the UTP-to-LTP loan is \$1,600 (80 percent \times \$2,000). LTP uses all of the proceeds received from UTP in the passive activity. UTP's distributive share of interest expense attributable to the UTP-to-LTP loan is \$500 (25 percent \times \$2,000). G's distributive share of interest expense attributable to the UTP-to-LTP loan is \$400 (80 percent \times \$500).

(ii) LTP has deductions for interest charged to LTP by UTP for the taxable year (LTP's self-charged interest deductions); G owns an indirect interest in LTP during LTP's taxable year and has gross income for the taxable year from interest charged to LTP by a passthrough entity (UTP) through which G owns an interest in LTP; and G's share of LTP's self-charged interest deductions includes passive activity deductions. Accordingly, paragraph (c) of this section

applies in determining G's passive activity gross income. See paragraph (c)(1) of this section.

(iii) Under paragraph (c)(2)(i) of this section, the applicable percentage of G's interest income is recharacterized as passive activity gross income from the activity. Paragraph (c)(3) of this section provides that the applicable percentage is obtained by dividing G's share for the taxable year of LTP's self-charged interest deductions that are treated as passive activity deductions from the activity (\$400) by the greater of G's share for the taxable year of LTP's self-charged interest deductions (\$400), or G's income for the year from interest charged to LTP (\$1,600). Thus, G's applicable percentage is 25 percent (\$400/\$1,600), and \$400 (25 percent \times \$1,600) of G's income from interest charged to LTP is treated as passive activity gross income from the passive activity that G conducts through UTP and LTP.

(iv) G's \$800 distributive share of the interest expense that UTP pays to the third-party lender is allocated under § 1.163-8T(c)(1) to an expenditure that is properly chargeable to capital account with respect to the loan to LTP. Thus, the expense is a deduction properly allocable to the interest income that G receives as a result of the UTP-to-LTP loan (see paragraph (f) of this section). Under paragraph (c)(2)(ii) of this section, the applicable percentage of G's deductions for the taxable year for interest expense that is properly allocable to G's income from interest charged by UTP to LTP is recharacterized as a passive activity deduction from LTP's passive activity. Accordingly, \$200 (25 percent \times \$800) of G's interest deduction is treated as a passive activity deduction from LTP's activity.

Example 6. (i) This *Example 6* illustrates the application of the rules of this section in the case of a taxpayer who conducts two passive activities through a passthrough entity. J, a calendar year taxpayer, is the 100-percent shareholder of Y, a calendar year S corporation. J conducts two passive activities through Y: a rental activity and a trade or business activity in which J does not materially participate. Y borrows \$80,000 from J, and uses \$60,000 of the loan proceeds in the rental activity and \$20,000 of the loan proceeds in the passive trade or business activity. Y pays \$8,000 of interest to J for the taxable year, and J incurs \$8,000 of interest expense as J's distributive share of Y's interest expense.

(ii) Y has self-charged interest deductions for the taxable year (i.e., the deductions for interest charged to Y by J); J owns a direct interest in Y during Y's taxable year and has gross income for J's taxable year from interest charged to Y; and J's share of Y's self-charged interest deductions includes passive activity deductions. Accordingly, paragraph (c) of this section applies in determining J's passive activity gross income. See paragraph (c)(1) of this section.

(iii) Under paragraph (c)(2)(i) of this section, the applicable percentage of J's interest income is recharacterized as passive activity gross income attributable to the rental activity. Paragraph (c)(3) of this section provides that the applicable percentage is

obtained by dividing J's share for the taxable year of Y's self-charged interest deductions that are treated as passive activity deductions from the rental activity (\$6,000) by the greater of J's share for the taxable year of Y's self-charged interest deductions (\$8,000), or J's income for the taxable year from interest charged to Y (\$8,000). Thus, J's applicable percentage is 75 percent (\$6,000/\$8,000), and \$6,000 (75 percent \times \$8,000) of J's income from interest charged to Y is treated as passive activity gross income from the rental activity J conducts through Y.

(iv) Under paragraph (c)(2)(i) of this section, the applicable percentage of J's interest income is recharacterized as passive activity gross income attributable to the passive trade or business activity. Paragraph (c)(3) of this section provides that the applicable percentage is obtained by dividing J's share for the taxable year of Y's self-charged interest deductions that are treated as passive activity deductions from the passive trade or business activity (\$2,000) by the greater of J's share for the taxable year of Y's self-charged interest deductions (\$8,000), or J's income for the taxable year from interest charged to Y (\$8,000). Thus, J's applicable percentage is 25 percent (\$2,000/\$8,000), and \$2,000 of J's income from interest charged to Y is treated as passive activity gross income from the passive trade or business activity J conducts through Y.

Par. 4. Section 1.469-11 is amended as follows:

1. Paragraph (a)(3) is amended by removing the language "and" at the end of the paragraph.

2. Paragraph (a)(4) is redesignated as paragraph (a)(5) and a new paragraph (a)(4) is added.

3. The paragraph headings for (c)(1) and (c)(1)(i) are revised.

4. Paragraph (c)(1)(iii) is added.

5. The added and revised provisions read as follows:

§ 1.469-11 Effective date and transition rules.

(a) * * *

(4) The rules contained in § 1.469-7 apply for taxable years ending after December 31, 1986; and

* * * * *

(c) * * *

(1) *Application of certain income recharacterization rules and self-charged rules*—(i) *Certain recharacterization rules inapplicable in 1987.* * * *

* * * * *

(iii) *Self-charged rules.* For taxable years beginning before June 4, 1991—

(1) A taxpayer is not required to apply the rules in § 1.469-7 in computing the taxpayer's passive activity loss and passive activity credit; and

(2) A taxpayer that owns an interest in a passthrough entity may use any reasonable method of offsetting items of interest income and interest expense

from lending transactions between the passthrough entity and its owners or between identically-owned passthrough entities (as defined in § 1.469-7(e)) to compute the taxpayer's passive activity loss and passive activity credit. Items from nonlending transactions cannot be offset under the self-charged rules.

* * * * *

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 5. The authority citation for the part 602 continues to read:

Authority: 26 U.S.C. 7805.

Par. 6. In § 602.101, paragraph (b) is amended by adding the following entry in numerical order to the table to read as follows:

§ 602.101 OMB Control Numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	* * * * *
1.469-7	1545-1244
* * * * *	* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: July 31, 2002.

Pamela F. Olson,

Acting Assistant Secretary of the Treasury.

[FR Doc. 02-21203 Filed 8-20-02; 8:45 am]

BILLING CODE 4830-01-P

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Part 811

[CSOSA-0005-I]

RIN 3225-AA03

District of Columbia Sex Offender Registration

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Interim Rule.

SUMMARY: The Court Services and Offender Supervision Agency for the District of Columbia ("CSOSA") is issuing interim regulations that set forth procedures and requirements relating to the registration of sex offenders, verification of the information maintained on sex offenders, and

reporting of changes in that information. These regulations carry out responsibilities of CSOSA under federal and District of Columbia law.

DATES: Effective August 21, 2002; comments must be submitted by October 21, 2002; incorporation by reference of publications listed in the regulation is approved by the Director of the Federal Register as of August 21, 2002.

ADDRESSES: Office of the General Counsel, CSOSA, Room 1253, 633 Indiana Avenue, NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Records Manager (telephone (202) 220-5359; e-mail roy.nanovic@csosa.gov).

SUPPLEMENTARY INFORMATION: The Court Services and Offender Supervision Agency for the District Of Columbia ("CSOSA") is adopting interim regulations on the registration of sex offenders (28 CFR part 811).

Under the Sex Offender Registration Act of 1999 ("SORA" or "Act", D.C. Law 13-137, D.C. Official Code sections 22-4001 *et seq.*), and section 166(a) of the Consolidated Appropriations Act, 2000 (Pub. L. 106-113 section 166(a), 113 Stat. 1530; D.C. Official Code section 24-133(c)(5)), CSOSA is responsible for carrying out sex offender registration functions in the District of Columbia, including maintaining and operating the sex offender registry. The sex offender registry contains information about sex offenders who live, reside, work, or attend school in the District of Columbia. Information about sex offenders and photographs, fingerprints, and supporting documents are provided by CSOSA to the Metropolitan Police Department, which is responsible for disclosing information about registered sex offenders to the public in conformity with District of Columbia laws and regulations. Appropriate information is also transmitted to the FBI, which operates the National Sex Offender Registry, and to sex offender registration authorities in other jurisdictions. This system is designed to further public safety by facilitating effective law enforcement, enabling members of the public to take lawful measures to protect themselves and their families, and reducing offenders' exposure to temptation to commit more crimes.

CSOSA is adopting these interim regulations, which exercise and implement powers and authorities of CSOSA under existing Federal and District of Columbia laws and District of Columbia regulations, in order to fully

effectuate the registration system and inform sex offenders and other members of the public of the requirements for registration. These regulations adopt and incorporate related regulations promulgated by the District of Columbia government, 6A DCMR sections 400 *et seq.*; include a statement of applicability; identify laws which provide for official notice to sex offenders concerning their obligation to register, but make it clear that lack of notice does not excuse a failure to register; discuss facts on which a determination of a person's obligation to register, the length of registration, and the notification classification may be based; authorize suspension of registration requirements during any period in which a sex offender is detained, incarcerated, confined, civilly committed, or hospitalized in a secure facility; set forth the duration of registration and the method for calculating a ten-year registration period; detail the obligations of sex offenders and CSOSA for initial registration; describe what a person must do to obtain judicial review of a determination that the person must register, or of a determination of the person's classification for purposes of registration or notification; detail the procedures and time limits for verification and reporting changes in registration information; provide alternatives for sex offenders who cannot comply with the time limits; describe the penalties for failing to comply with the Sex Offender Registration Act of 1999 or any procedures, requirements, rules, or regulations promulgated under the Act; and notify sex offenders where they are to direct information in writing or to appear in person.

Matters of Regulatory Procedure

Administrative Procedure Act

The implementation of these regulations as interim regulations, with provision for post-promulgation public comments, is based on the "good cause" exceptions found at 5 U.S.C. 553(b)(3)(B) and (d)(3). The regulations implement, in part, section 166(a) of the Consolidated Appropriations Act, 2000 (Pub. L. 106–113 section 166(a), 113 Stat. 1530; D.C. Official Code section 24–133(c)(5)), which directs CSOSA to carry out sex offender registration functions in the District of Columbia, and various provisions of District of Columbia law and regulations, including sections 3, 8, 9 and 10 of the Sex Offender Registration Act of 1999 (D.C. Official Code section 22–4002, 4007, 4008 & 4009) and 6A DCMR

sections 405.1, 409.1, 409.2, 410.1, which grant CSOSA the authority to make certain decisions and to adopt procedures and requirements relating to sex offender registration in the District of Columbia.

As stated in the report of the District of Columbia Council's Judiciary Committee for the District's Sex Offender Registration Act, "[a] sex offender registration and notification program, if appropriately designed and effectively implemented, can promote public safety in at least three ways: by facilitating effective law enforcement; by enabling members of the public to take direct measures of a lawful nature for the protection of themselves and their families; and by reducing registered offenders' exposure to temptation to commit more offenses." Committee on the Judiciary, Report on Bill 13–250, The Sex Offender Registration Act of 1999, at 3 (Nov. 15, 1999). Given the importance of having accurate, complete, and up-to-date information about sex offenders available to both law enforcement officials and to the public, and the fact that the formulation of implementing regulations closely follows the statutory framework and existing District of Columbia regulations, it is impracticable and unnecessary to adopt this rule with the prior notice and comment period normally required under 5 U.S.C. 553(b) or with the delayed effective date normally required under 5 U.S.C. 553(d). Moreover, as noted, the collection of sex offender registration information and its release to law enforcement and other agencies and the public pursuant to the Sex Offender Registration Act of 1999 furthers important public safety interests by facilitating the solution and prevention of crime by law enforcement, enabling lawful community self-protection measures, and reducing the temptation for recidivism. Delay in the full implementation of the law—including the ability to prosecute and take other actions in relation to sex offenders who fail to comply with its requirements—would thwart or delay the realization of these public safety benefits. Therefore, it would be contrary to the public interest to adopt these regulations with the prior notice and comment period normally required under 5 U.S.C. 553(b) or with the delayed effective date normally required under 5 U.S.C. 553(d).

For the foregoing reasons, CSOSA is issuing these regulations without any delay in their effectiveness as an interim rule and without a prior notice of proposed rulemaking. Any interested person, however, who wishes to submit comments on the interim rule may do so

by writing or e-mailing the agency at the addresses given above in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** captions. CSOSA will consider comments received during the comment period before taking final action on the interim rule. Comments received after the expiration of the comment period will be considered to the extent practicable. All comments received remain on file for public inspection at the above address.

Executive Order 12866

This rule has been determined to be significant under Executive Order 12866 and has been reviewed by the Office of Management and Budget (OMB).

Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, the Director of CSOSA has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director of CSOSA, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule and by approving it certifies that this rule will not have a significant economic impact upon a substantial number of small entities. This rule pertains to agency management, and its economic impact is limited to the agency's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, the Director of CSOSA has determined that no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment,

productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Plain Language Instructions

If you have suggestions on how to improve the clarity of these regulations, write, e-mail, or call the Records Manager (Roy Nanovic) at the address or telephone number given above in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** captions.

List of Subjects in 28 CFR Part 811

Incorporation by Reference; Probation and Parole.

Paul A. Quander, Jr.,
Director.

Accordingly, we amend chapter VIII, Title 28 of the Code of Federal Regulations by adding a new Part 811 as set forth below.

PART 811—SEX OFFENDER REGISTRATION

Sec.

- 811.1 Purpose and scope; relation to District of Columbia regulations.
- 811.2 Applicability.
- 811.3 Notice of obligation to register.
- 811.4 Determination of the obligation to register and the length of registration.
- 811.5 Commencement of the obligation to register.
- 811.6 Duration of the obligation to register.
- 811.7 Initial registration.
- 811.8 Review of determination to register.
- 811.9 Periodic verification of registration information.
- 811.10 Changes in registration information.
- 811.11 Compliance.
- 811.12 Penalties.
- 811.13 Notices and appearances.
- 811.14 Definitions.

Appendix A to Part 811—Listing of Sex Offender Registration Offenses by Class

Authority: 5 U.S.C. 301; Pub. L. 105–33, 111 Stat. 251; Pub. L. 106–113, sec. 166(a), 113 Stat. 1530

§ 811.1 Purpose and scope; relation to District of Columbia regulations.

(a) In accordance with its sex offender registration functions authorized by section 166(a) of the Consolidated Appropriations Act, 2000 (Pub. L. 106–113, sec. 166(a), 113 Stat. 1530; D.C. Official Code secs. 24–133(c)(5)) and as further authorized by the Sex Offender Registration Act of 1999 (“the Act,” D.C. Law 13–137, D.C. Official Code, secs. 22–4001 *et seq.*), the Court Services and Offender Supervision Agency for the District of Columbia (“CSOSA”) operates and maintains the sex offender registry for the District of Columbia. The regulations in this part set forth procedures and requirements relating to

registration, verification, and changes in information for sex offenders who live, reside, work, or attend school in the District of Columbia.

(b) Chapter 4 of Title 6A, District of Columbia Municipal Regulations (DCMR)(47 D.C. Reg. 10042, December 22, 2000), contains regulations issued by the government of the District of Columbia for the sex offender registration system in the District of Columbia (“District of Columbia regulations”). Chapter 4 of Title 6A, DCMR (47 D.C. Reg. 10042, December 22, 2000) is incorporated by reference in this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Chapter 4 of Title 6A, DCMR, is available for inspection at the Office of the Federal Register, 800 N. Capitol Street, NW., Suite 700, Washington, DC. Copies of Chapter 4 of Title 6A, DCMR, may be obtained from the District of Columbia’s Office of Documents and Administrative Issuances, 441 4th Street, NW., Room 520S, Washington, DC 20001. CSOSA hereby adopts all powers and authorities that the District of Columbia regulations authorize CSOSA to exercise, and hereby adopts all procedures and requirements that the District of Columbia regulations state that CSOSA shall adopt or carry out, including but not limited to all such powers, authorities, procedures and requirements relating to registration, verification, and changes in information.

§ 811.2 Applicability.

(a) Sex offender registration requirements apply to all persons who live, reside, work, or attend school in the District of Columbia, and who:

- (1) committed a registration offense on or after July 11, 2000;
- (2) committed a registration offense at any time and were in custody or under supervision on or after July 11, 2000;
- (3) were required to register under the law of the District of Columbia as was in effect on July 10, 2000; or
- (4) committed a registration offense at any time in another jurisdiction and, within the registration period (see §§ 811.5 and 811.6), entered the District of Columbia to live, reside, work or attend school.

(b) “Committed a registration offense” means that a person was found guilty or found not guilty by reason of insanity of a registration offense or was determined to be a sexual psychopath. Registration offenses are defined in section 2(8) of the Sex Offender Registration Act of 1999 (D.C. Official Code § 22–4001(8)), subject to the exceptions in section

17(b) of that Act (D.C. Official Code section 22–4016), and are listed descriptively in the Appendix to Part 811 (which also provides information on registration and notification classes). Any future revision to the statutory provisions designating registration offenses will be effective notwithstanding the timing of any conforming revision of these regulations, including the Appendix.

§ 811.3 Notice of obligation to register.

(a) Sex offenders may be notified of their obligation to register under various provisions of law. See sections 4, 6 and 8 of the Sex Offender Registration Act of 1999 (D.C. Official Code sections 22–4003, 4005, 4007) (relating to notice by the District of Columbia Superior Court, Department of Corrections, or CSOSA); 18 U.S.C. 4042(c) (relating to notice by Federal Bureau of Prisons and probation offices); 18 U.S.C. 3563(a)(8), 3583(d), 4209(a) (inclusion of registration requirements as conditions of release under federal law); 42 U.S.C. 14071(b)(1) (notice under federal law standards for state sex offender registration programs).

(b) In some cases, sex offenders may not be notified of their obligation to register. Lack of notice does not excuse a failure to register because sex offenders have an independent obligation to register. Persons who have been convicted or found not guilty by reason of insanity of a sex offense or who have been determined to be a sexual psychopath should report to CSOSA in order to ascertain whether they are required to register.

§ 811.4 Determination of the obligation to register and the length of registration.

(a) If the Superior Court finds that a person committed a registration offense, the Superior Court enters an order certifying that the person is a sex offender and that the person is subject to registration for a prescribed period of time (see § 811.6).

(b) If a court order has not been entered certifying that a person is a sex offender and that the person is subject to registration for a prescribed period of time, CSOSA makes those determinations. CSOSA also determines the notification classification if the Court has not done so. Facts on which CSOSA’s determination may be based include:

- (1) The offense or offenses of conviction (or finding of not guilty by reason of insanity) or a determination that the person is a sexual psychopath;
- (2) For certain offenses, facts that may not be apparent on the face of the

conviction (or finding of not guilty by reason of insanity), such as:

- (i) the age of the victim;
- (ii) whether force was involved; or
- (iii) whether the offense involved an undercover law enforcement officer who was believed to be an adult;
- (3) Prior criminal history;
- (4) For an offense committed in or prosecuted under the law of another jurisdiction, whether the offense involved conduct that was the same as or substantially similar to a District of Columbia registration offense; and
- (5) The amount of time that has elapsed as computed under § 811.6.

§ 811.5 Commencement of the obligation to register.

(a) A sex offender's obligation to register starts when the sex offender is found guilty or not guilty by reason of insanity of a registration offense or is determined to be a sexual psychopath. However, CSOSA may suspend registration requirements during any period of time in which a sex offender is detained, incarcerated, confined, civilly committed, or hospitalized in a secure facility.

(b) A sex offender must register if the sex offender is placed on probation, parole, supervised release, or convalescent leave, is conditionally or unconditionally released from a secure facility, is granted unaccompanied grounds privileges or other unaccompanied leave, absconds or escapes, is otherwise not detained, incarcerated, confined, civilly committed, or hospitalized in a secure facility, or enters the District of Columbia from another jurisdiction to live, reside, work, or attend school. Registration shall be effectuated as provided in § 811.7 and may be carried out prior to the occurrence of a circumstance described in this paragraph, including the release of or granting of leave to a sex offender.

§ 811.6 Duration of the obligation to register.

(a) *Lifetime registration.* The registration period for a sex offender who is required to register for life shall end upon the sex offender's death.

(b) *Term of years registration.* (1) The registration period for any other sex offender shall end upon the expiration of the sex offender's probation, parole, supervised release, conditional release, or convalescent leave, or ten years after the sex offender is placed on probation, parole, supervised release, conditional release, or convalescent leave, or is unconditionally released from a correctional facility, prison, hospital or other place of confinement, whichever is latest.

(2) In computing ten years, CSOSA will not count:

(i) Any time in which the sex offender has failed to register or otherwise failed to comply with requirements of the Act or any procedures, requirements, rules, or regulations promulgated under the Act, including these regulations and the District of Columbia regulations;

(ii) Any time in which a sex offender is detained, incarcerated, confined, civilly committed, or hospitalized in a mental health facility; and

(iii) Any time in which a sex offender was registered prior to a revocation of probation, parole, supervised release, conditional release, or convalescent leave.

(3) In computing ten years, CSOSA will count any time in which a sex offender was registered in another jurisdiction unless that time is not counted because of a circumstance set forth in paragraph (b)(2) of this section.

(c) *Reversal, vacation, or pardon.* A person's obligation to register terminates if the person's conviction, finding of not guilty by reason of insanity, or finding that the person is a sexual psychopath is reversed or vacated, or if the person has been pardoned for the offense on the ground of innocence, and the person has committed no other offenses for which registration is required.

(d) *Termination of obligation to register in the District of Columbia under other circumstances.* A sex offender's obligation to register in the District of Columbia terminates if the sex offender no longer lives, resides, works or attends school in the District of Columbia. However, the obligation to register in the District of Columbia resumes if the sex offender re-enters the District of Columbia within the registration period to live, reside, work or attend school.

§ 811.7 Initial registration.

(a) *Duties of sex offender.* (1) A sex offender must notify CSOSA within 3 days of the occurrence of any circumstance described in § 811.5(b), including but not limited to being sentenced to probation, being released (including any escape or abscondance) from incarceration or confinement, or entering the District of Columbia to live, reside, work, or attend school.

(2) A sex offender must meet with a responsible officer or official, as directed by CSOSA, for the purpose of registration, and must cooperate in such a meeting, including:

(i) Providing any information required for registration and cooperating in photographing and fingerprinting;

(ii) Reviewing information obtained by CSOSA pursuant to paragraph (b) of

this section as CSOSA directs and either attesting to its accuracy or setting forth in writing, under penalties of perjury, the exact portion or portions that are not accurate; and

(iii) Acknowledging receipt of information concerning the sex offender's duties under the Act, including reading (or, if the sex offender cannot read, listening to a reading of) and signing a form or forms stating that these duties have been explained to the sex offender.

(3) In case of disagreement with CSOSA's determination that the person must register or with CSOSA's determination of the person's classification for purposes of registration or notification, the person must follow the review procedures set forth in § 811.8.

(b) *Duties of CSOSA.* (1) CSOSA shall obtain information relating to the sex offender for the purpose of registration including:

(i) Name(s) and alias(es);

(ii) Date of birth;

(iii) Physical description such as sex, race, height, weight, eye color, hair color, tattoos, scars, or other marks or characteristics;

(iv) Social security, PDID, DCDC and FBI numbers;

(v) Driver's license number and make, model, color, and license plate number of any motor vehicle(s) the sex offender owns;

(vi) A photograph and set of fingerprints;

(vii) Current and/or anticipated home, school, work address(es) and telephone number(s); and

(viii) Other information that may assist CSOSA or the Metropolitan Police Department in locating the sex offender.

(2) CSOSA shall also obtain a detailed description of the offense(s) on the basis of which a sex offender is required to register, the presentence report(s), the victim impact statement(s), the date(s) of conviction and any sentence(s) imposed, the sex offender's criminal record and a detailed description of any relevant offense or offenses, pertinent statutes and case law in other jurisdictions, and any other information it deems useful in order to determine a sex offender's obligation to register, term of registration, and notification classification, to verify the accuracy of the information provided, to assist other jurisdictions' sex offender registration agencies and authorities, or to assist the Metropolitan Police Department in its law enforcement functions.

(3) CSOSA shall inform a sex offender of the sex offender's duty to:

(i) Comply with the requirements set forth in paragraph (a) of this section for initial registration;

(ii) Periodically verify the address(es) at which the sex offender lives, resides, works, and/or attends school, and other information, as provided in § 811.9;

(iii) Report any change of address and any other changes in registration information (including changes in appearance), as provided in § 811.10;

(iv) Notify CSOSA if the sex offender is moving to another jurisdiction or works or attends school in another jurisdiction and to register in any such jurisdiction; and

(v) Comply with the requirements of the Act and any procedures, requirements, rules, or regulations promulgated under the Act, including these regulations and the District of Columbia regulations.

(4) CSOSA shall inform the sex offender of the penalties for failure to comply with the sex offender's duties.

(5) If the Superior Court has not entered an order certifying that a person is a sex offender, CSOSA shall inform the person that, if the person disagrees with CSOSA's determination that the person must register or CSOSA's determination of the person's classification for purposes of registration or notification, then the person must follow the review procedures set forth in § 811.8. CSOSA shall provide the person with a form to notify CSOSA of an intent to seek such review.

§ 811.8 Review of determination to register.

(a) If a person, other than a person who has been certified as a sex offender by the Court, disagrees with CSOSA's determination that the person is subject to registration or with CSOSA's determination of the person's classification for purposes of registration or notification, the person may seek judicial review of the determination, subject to the limitations of section 5(a)(1) of the Act (D.C. Official Code § 22-4004(a)(1)), by:

(1) Immediately providing CSOSA with a notice of intent to seek review upon being informed of the determination; and

(2) Within 30 calendar days of the date on which the person is informed of CSOSA's determination, filing a motion in the Superior Court setting forth the disputed facts and attaching any documents or affidavits upon which the person intends to rely.

(b) A person who fails to comply with paragraph (a) of this section may seek review of CSOSA's determination only in conformity with the limitations of

section 5(a)(1) of the Act (D.C. Official Code Section 4004(a)(1)) and for good cause shown and to prevent manifest injustice by filing a motion in the Court within three years of the date on which the person is informed of CSOSA's determination.

§ 811.9 Periodic verification of registration information.

(a) Sex offenders who are required to register for life must verify registration information quarterly pursuant to the procedures set forth in paragraph (d) of this section.

(b) All other sex offenders must verify registration information annually pursuant to the procedures set forth in paragraph (d) of this section.

(c) Quarterly or annually, as appropriate, CSOSA will mail a verification form to the home address of the sex offender.

(d) The sex offender must correct any information on the form which is inaccurate or out of date and must sign, thumb-print, and return the form to CSOSA no later than 14 calendar days after the date on which CSOSA placed it in the mail. The sex offender has the option of returning the form by mail or in person unless:

(1) The sex offender is also on probation, parole, or supervised release or otherwise must report to CSOSA, and CSOSA directs the sex offender to verify the registration information in person;

(2) CSOSA directs the sex offender to appear in person because the sex offender has previously failed to submit a timely verification or submitted an incomplete or inaccurate verification; or

(3) CSOSA directs the sex offender to appear in person for the purpose of taking a new photograph documenting a significant change in physical appearance or updating a photograph that is five or more years old.

§ 811.10 Changes in registration information.

(a)(1) A sex offender must notify CSOSA if the sex offender:

(i) Ceases to live or reside at the registered address or moves to a different address;

(ii) leaves a job or obtains a new job, or leaves a school or enrolls in a new school; or

(iii) ceases to own or becomes an owner of any motor vehicle.

(2) A sex offender must notify CSOSA if there is a significant change in the sex offender's appearance and report as directed for the purpose of having a new photograph taken. Any question regarding whether a change in physical appearance is significant is to be referred to CSOSA.

(3) A sex offender must notify CSOSA if the sex offender is moving to another jurisdiction or if the sex offender works or attends school in another jurisdiction and must register in any such jurisdiction.

(b) Notice of the changes described in paragraph (a) of this section must be in writing and must be provided prior to the change if feasible and in any event within three days of the change. Notices of change in address or place of work or school attendance must include new address, location, and phone number information. Notice relating to ownership of a motor vehicle must include the make, model, color, and license plate number of the vehicle.

§ 811.11 Compliance.

(a) A sex offender may be excused from strict compliance with the time limits set forth in these regulations if the sex offender notifies CSOSA in advance of circumstances that will interfere with compliance and makes alternative arrangements to satisfy the requirements or, in the case of an emergency, notifies CSOSA as soon as the sex offender is able to do so.

(b) CSOSA may direct that a sex offender meet with a responsible officer or official for the purpose of securing compliance or discussing non-compliance with any requirements of the Act or any procedures, requirements, rules, or regulations promulgated under the Act, including these regulations and the District of Columbia regulations.

§ 811.12 Penalties.

A violation of the requirements of the Act or any procedures, requirements, rules, or regulations promulgated under the Act, including these regulations and the District of Columbia regulations, may result in criminal prosecution under section 16 of the Act (D.C. Official Code Section 22-4015), revocation of probation, parole, supervised release, or conditional release, and extension of the registration period under § 811.6(b)(2).

§ 811.13 Notices and appearances.

Unless otherwise directed by the Court or CSOSA,

(a) Notices or reports that are required to be submitted in writing should be sent to: Sex Offender Registration Unit, Court Services and Offender Supervision Agency, Room 2002, 300 Indiana Avenue, NW., Washington, DC 20001.

(b) A person who is required to report in person should go to: Sex Offender Supervision Office, Court Services and Offender Supervision Agency, Room

2002, 300 Indiana Avenue, NW., Washington, DC 20001.

§ 811.14 Definitions.

(a) The terms “attends school,” “Court,” “in custody or under supervision,” “sex offender,” and “works” shall have the same meaning as set forth in Section 2 of the Sex Offender Registration Act of 1999 (D.C. Official Code Section 22–4001).

(b) The term “the Act” means the Sex Offender Registration Act of 1999 (D.C. Official Code Section 22–4001 *et seq.*).

(c) The term “days” means business days unless otherwise specified.

(d) In relation to a motor vehicle, the term “owns” includes both exclusive ownership and co-ownership, and the term “owner” includes both exclusive owners and co-owners.

Appendix A to Part 811—Listing of Sex Offender Registration Offenses by Class

Class A Offenders—All Lifetime Registrants

(D.C. Official Code Secs. 22–4001(6), 4002(b), 4011(b)(2)(A))

1. Class A includes offenders who have been convicted or found not guilty by reason of insanity of:

- (a) First degree sexual abuse;
- (b) Second degree sexual abuse;
- (c) Rape;
- (d) Forcible sodomy;
- (e) First degree child sexual abuse committed against a child under 12;
- (f) Carnal knowledge (statutory rape) committed against a child under 12;
- (g) Sodomy committed against a child under 12;
- (h) Murder committed before, during, or after engaging in or attempting to engage in a sexual act or contact or rape;
- (i) Manslaughter committed before, during, or after engaging in or attempting to engage in a sexual act or contact or rape;
- (j) Attempting to commit any of the foregoing offenses;
- (k) Conspiring to commit any of the foregoing offenses; or
- (l) Assault with intent to commit any of the foregoing offenses.

2. Class A also includes offenders who:

- (a) In two or more trials or plea proceedings, have been convicted or found not guilty by reason of insanity of a felony registration offense or any registration offense against a minor. (Recidivism).

(b) In a single trial or plea proceeding, have been convicted or found not guilty by reason of insanity of registration offenses against two or more victims where each offense is a felony or committed against a minor (Multiple victims).

(c) Have been determined to be sexual psychopaths.

3. Class A also includes offenders who have been convicted or found not guilty by reason of insanity under the law of another jurisdiction of offenses that involved conduct that is the same as or substantially similar to that above.

Class B Offenders—“Ten Year” Registrants

(Other Offenses Against Minors, Wards, Patients, or Clients)

(D.C. Official Code Secs. 22–4001(8), 4002(a), 4011(b)(2)(B))

1. Class B includes offenders who are not included in Class A and have been convicted or found not guilty by reason of insanity of any of the following crimes against a minor (that is, a person under the age of 18):

- (a) Third degree sexual abuse;
- (b) Fourth degree sexual abuse;
- (c) Misdemeanor sexual abuse;
- (d) First degree child sexual abuse;
- (e) Second degree child sexual abuse;
- (f) Carnal knowledge (statutory rape);
- (g) Sodomy committed against a minor;
- (h) Indecent acts on a child;
- (i) Enticing a child;
- (j) Lewd, indecent or obscene acts;
- (k) Sexual performance using a minor;
- (l) Incest;
- (m) Obscenity;
- (n) Prostitution/Pandering;
- (o) Assault (unwanted sexual touching);
- (p) Threatening to commit a sexual offense;
- (q) First or second degree burglary with intent to commit sex offense;
- (r) Kidnapping (does not require a sexual purpose);
- (s) Assault with intent to commit any of the foregoing offenses;
- (t) Attempting to commit any of the foregoing offenses;
- (u) Conspiring to commit any of the foregoing offenses; or
- (v) Any offense against a minor for which the offender agreed in a plea agreement to be subject to sex offender registration requirements.

2. Class B also includes offenders who are not included in Class A and have been convicted or found not guilty by reason of insanity of any of the following crimes regardless of the age of the victim:

- (a) First degree sexual abuse of a ward or resident of a hospital, treatment facility or other institution.
- (b) Second degree sexual abuse of a ward or resident of a hospital, treatment facility or other institution.
- (c) First degree sexual abuse of a patient or client.
- (d) Second degree sexual abuse of a patient or client.

3. Class B also includes offenders who are not included in Class A and have been convicted or found not guilty by reason of insanity under the law of another jurisdiction of offenses that involved conduct that is the same as or substantially similar to that above.

Class C Offenders—“Ten Year” Registrants

(Other Offenses Against Adult Victims)

(D.C. Official Code Secs. 22–4001(8), 4002(a), 4011(b)(2)(C))

1. Class C includes offenders who are not included in Class A or Class B and have committed any of the following crimes against an adult (that is, a person 18 years of age or older):

- (a) Third degree sexual abuse;
- (b) Fourth degree sexual abuse;

(c) First or second degree burglary with intent to commit sex offense;

(d) Kidnapping with intent to commit sex offense;

(e) Threatening to commit a sexual offense (felony);

(f) Assault with intent to commit any of the foregoing offenses;

(g) Attempting to commit any of the foregoing offenses;

(h) Conspiring to commit any of the foregoing offenses, or;

(i) Any offense for which the offender agreed in a plea agreement to be subject to sex offender registration requirements.

2. Class C also includes offenders who are not included in Class A or Class B and have been convicted or found not guilty by reason of insanity under the law of another jurisdiction of offenses that involved conduct that is the same as or substantially similar to that above.

Exceptions (D.C. Official Code Sec. 22–4016(b))

The following do not constitute registration offenses:

1. Any sexual offense between consenting adults or an attempt, conspiracy or solicitation to commit such an offense, except for offenses to which consent is not a defense as provided in Section 218 of the Anti-Sexual Abuse Act of 1994 (D.C. Official Code § 22–3017).

2. Any misdemeanor offense that involved a person’s sexual touching or attempted or solicited sexual touching of an undercover law enforcement officer where the person believed that the officer was an adult.

3. Any misdemeanor offense committed against an adult, except where the offender agrees in a plea agreement to be subject to sex offender registration requirements.

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COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Part 812

[CSOSA–0006–I]

RIN 3225–AA04

Collection and Use of DNA Information

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Interim Rule.

SUMMARY: The Court Services and Offender Supervision Agency for the District of Columbia (“CSOSA”) is adopting interim regulations to implement section 4 of the DNA Analysis Backlog Elimination Act of 2000, in conjunction with District of Columbia laws enacted pursuant to that Act which specify qualifying District of Columbia offenses for purposes of DNA

sample collection. The interim regulations set forth the responsibilities of CSOSA for collecting DNA samples from individuals under its supervision who have been convicted of specific offenses identified by District of Columbia statute. The regulations specify that DNA samples are to be collected, handled, preserved, and submitted to the Federal Bureau of Investigation ("FBI") in accordance with FBI guidelines for inclusion in the Combined DNA Index System ("CODIS"), a national database of DNA profiles from convicted offenders, unsolved crime scenes, and missing persons. The regulations also specify that CSOSA will cooperate with the Federal Bureau of Prisons to ensure that unnecessary samples will not be collected; establish a standard for what constitutes an individual's refusal to cooperate in the collection of a DNA sample; and define what steps CSOSA deems to be reasonably necessary to take when an individual refuses to cooperate. The regulations identify in an appendix the offenses which qualify for DNA collection, as they appear in the District of Columbia public laws, in the District of Columbia Code (1981 *ed.*), and in the District of Columbia Official Code (2001 *ed.*).

DATES: Effective August 21, 2002; comments must be submitted by October 21, 2002.

ADDRESSES: Office of the General Counsel, CSOSA, Room 1253, 633 Indiana Avenue, NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Records Manager (telephone: (202) 220-5359; e-mail: roy.nanovic@csosa.gov).

SUPPLEMENTARY INFORMATION: The Court Services and Offender Supervision Agency for the District of Columbia ("CSOSA") is adopting interim regulations on the collection and use of DNA information (28 CFR part 812).

The DNA Analysis Backlog Elimination Act of 2000 (Pub. L. 106-546, 114 Stat. 2726) authorizes the collection of DNA samples from persons convicted of "qualifying District of Columbia offenses" who are in the custody of the Federal Bureau of Prisons ("BOP") or who are on supervised release, parole, or probation and under CSOSA's supervision. Qualifying District of Columbia offenses were identified by the Council of the District of Columbia in the DNA Sample Collection Act of 2001, District of Columbia Act 14-076, the DNA Sample Collection Emergency Act of 2001, District of Columbia Act 14-077, and the DNA Sample Collection

Congressional Review Emergency Act of 2001, District of Columbia Act 14-130.

The DNA information becomes part of the Combined DNA Index System ("CODIS"), a national database of DNA profiles from convicted offenders, unsolved crime scenes, and missing persons. CODIS allows State and local forensic laboratories to exchange and compare DNA profiles electronically, thereby linking serial violent crimes, especially sexual assaults, to each other, and to identify suspects by matching DNA from crime scenes to convicted offenders.

CSOSA is responsible for the supervision of adults on probation, parole, or supervised release for District of Columbia Code offenses in the District of Columbia. Under the provisions of the DNA Analysis Backlog Elimination Act of 2000, CSOSA must collect a DNA sample from each individual under its supervision who is, or has been, convicted of a qualifying District of Columbia offense. CSOSA has the discretion not to collect a sample from the individual if CODIS already has a DNA analysis for the individual. CSOSA also has the authority to use such means as are reasonably necessary to collect a sample from an individual who refuses to cooperate in the collection of the sample.

CSOSA's regulations list the qualifying District of Columbia offenses in an appendix to the part. The offenses are listed in three tables. Table 1 presents the offenses as they were identified in the "DNA Sample Collection Act of 2001". Table 2 presents the offenses in numerical order under the D.C. Code, (1981 Edition). Table 3 presents the offenses in numerical order under the D.C. Official Code (2001 Edition). These tables are presented for informational purposes only. Any future revision to the District of Columbia Code sections designating the qualifying offenses will be effective notwithstanding the timing of a conforming revision of the appendix by CSOSA.

Section 812.2 of CSOSA's interim regulations establishes procedures for coordinating the collection of samples with BOP. BOP has the authority to collect DNA samples from District of Columbia Code offenders in its custody. CSOSA will exchange information concerning the collection of the DNA sample from District of Columbia Code offenders in their custody or under their supervision in order to ensure that DNA samples will not be taken from District of Columbia Code offenders unnecessarily.

Section 812.4 pertains to collection procedures. Paragraph (a) specifies that

the DNA sample (currently in the form of a blood sample) will be collected in accordance with FBI guidelines.

Paragraph (b) establishes what CSOSA deems to be a refusal to cooperate by an individual who is subject to collection. Paragraph (c) describes what reasonably necessary measures CSOSA will take in response to such refusal, including administrative sanctions, referral for criminal prosecution, and a request for revocation of probation, parole, or supervised release which could result in commitment to the custody of the Federal Bureau of Prisons, thereby facilitating collection procedures authorized by Department of Justice regulations (28 CFR part 28).

Matters of Regulatory Procedure

Administrative Procedure Act

The implementation of these regulations as interim regulations, with provision for post-promulgation public comments, is based on the "good cause" exceptions found at 5 U.S.C. 553(b)(3)(B) and (d)(3). The rule implements section 4 of Pub. L. 106-546 (42 U.S.C. 14135b), which requires the Director of CSOSA to "collect a DNA sample from each individual under the supervision of the Agency who is on supervised release, parole, or probation who is, or has been, convicted of a qualifying District of Columbia offense" and requires collection of DNA samples to commence not later than 180 days after the effective date of the Act. Given that section 4(d) authorizes the government of the District of Columbia to "determine those offenses under the District of Columbia Code that shall be treated * * * as qualifying District of Columbia offenses," Congress must have been aware that it would not be feasible within a 180-day time period to enact the required District of Columbia legislation, publish a proposed regulation for notice and comment, as well as a subsequent final rule, and for the period of the final rule's delayed effective date to have run. Public Law 106-546, in conjunction with the District of Columbia legislation, is explicit and comprehensive concerning the types of offenses that will be treated as qualifying District of Columbia offenses and concerning the responsibilities of CSOSA in collecting DNA samples. In light of the short statutory time frame for the implementation of this law and the fact that the formulation of implementing regulations involves the exercise of relatively little discretion, it is impracticable and unnecessary to adopt this rule with the prior notice and comment period normally required

under 5 U.S.C. 553(b) or with the delayed effective date normally required under 5 U.S.C. 553(d).

Moreover, the collection, analysis, and indexing of DNA samples as required by Public Law 106–546 furthers important public safety interests by facilitating the solution and prevention of crime, *see* H.R. Rep. No. 900, 106th Cong., 2d Sess. 8–11 (2000) (House Judiciary Committee Report). Delay in the full implementation of the law—including the absence of a specification of what constitutes a refusal to cooperate in DNA sample collection and what measures are to be taken in response to such a refusal, as set forth in these regulations—would thwart or delay the realization of these public safety benefits. Dangerous offenders who might be successfully identified through DNA matching may reach the end of supervision before DNA sample collection can be carried out, thereby remaining at large to engage in further crimes against the public. Furthermore, delay in collecting, analyzing, and indexing DNA samples, and hence in the identification of offenders, may foreclose prosecution due to the running of statutes of limitations. Failure to identify, or delay in identifying, offenders as the perpetrators of crimes through DNA matching also increases the risk that innocent persons may be wrongfully suspected, accused, or convicted of such crimes. Therefore, it would be contrary to the public interest to adopt these regulations with the prior notice and comment period normally required under 5 U.S.C. 553(b) or with the delayed effective date normally required under 5 U.S.C. 553(d).

Any interested person who wishes to submit comments on the interim rule, however, may do so by writing or e-mailing the agency at the addresses given above in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** captions.

Executive Order 12866

This interim rule has been determined to be significant under Executive Order 12866 and has been reviewed by the Office of Management and Budget (OMB).

Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, the Director of CSOSA has determined that this rule does not have sufficient

federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director of CSOSA, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule and by approving it certifies that this rule will not have a significant economic impact upon a substantial number of small entities. This rule pertains to agency management, and its economic impact is limited to the agency's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, the Director of CSOSA has determined that no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Plain Language Instructions

We want to make CSOSA's documents easy to read and understand. If you have suggestions on how to improve the clarity of these regulations, write, e-mail, or call the Records Manager (Roy Nanovic) at the address or telephone number given above in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** captions.

List of Subjects in 28 CFR Part 812

Probation and Parole.

Paul A. Quander, Jr.,

Director.

Accordingly, we amend chapter VIII, Title 28 of the Code of Federal Regulations by adding new part 812 as set forth below.

PART 812—COLLECTION AND USE OF DNA INFORMATION

Sec.

812.1 Purpose.

812.2 Individuals subject to DNA collection.

812.3 Coordination with the Federal Bureau of Prisons.

812.4 Collection procedures.

Appendix A to Part 812—Qualifying District of Columbia Code Offenses

Authority: 5 U.S.C. 301; Pub. L. 106–546 (114 Stat. 2726).

§ 812.1 Purpose.

The Court Services and Offender Supervision Agency for the District of Columbia ("CSOSA") cooperates with other federal agencies to ensure that DNA samples from offenders are appropriately furnished to the Federal Bureau of Investigation ("FBI") for DNA analysis. The results of the DNA analyses are to be included in the Combined DNA Index System ("CODIS").

§ 812.2 Individuals subject to DNA collection.

CSOSA is responsible for collecting a DNA sample from each individual under its supervision who is, or has been, convicted of a qualifying District of Columbia Code offense. Qualifying District of Columbia Code offenses were designated by the Council of the District of Columbia in the "DNA Sample Collection Act of 2001." CSOSA provides a listing of these offenses in the Appendix to this part. The list is presented for informational purposes only. Any future revision to the District of Columbia Code sections designating the qualifying offenses will be effective notwithstanding the timing of a conforming revision of the Appendix by CSOSA. CSOSA may choose not to collect a sample from an individual if it determines that CODIS already contains a DNA analysis for the individual.

§ 812.3 Coordination with the Federal Bureau of Prisons.

(a) CSOSA will coordinate with the Federal Bureau of Prisons in order to obtain documentation regarding the collection of a DNA sample when the Federal Bureau of Prisons releases an inmate to CSOSA's supervision or as requested by CSOSA.

(b) CSOSA shall provide the Federal Bureau of Prisons with documentation regarding the collection of a DNA sample from a District of Columbia Code offender when CSOSA returns the District of Columbia Code offender to the custody of the Federal Bureau of Prisons or as requested by the Federal Bureau of Prisons.

§ 812.4 Collection procedures.

(a) DNA samples will be collected, handled, preserved, and submitted to

the FBI in accordance with FBI guidelines.

(b) CSOSA has the authority to use such means as are reasonably necessary to collect a sample from an individual who refuses to cooperate in the collection of the sample. Unless CSOSA determines that there are mitigating circumstances, CSOSA will consider that an individual is refusing to cooperate if:

(1) The individual is being ordered or transferred to CSOSA's supervision, but fails to report to CSOSA for collection of the sample within 15 business days of being sentenced to probation or being discharged from a correctional institution; or

(2) The individual is already under CSOSA supervision and has been notified by his or her Community Supervision Officer of the time to report for collection of the sample, but fails to report for collection of the sample; or

(3) The individual has reported to CSOSA for collection of the sample, but fails to provided the sample after being given a minimum of one hour to do so; or

(4) The individual specifically states that he or she will not cooperate.

(c) When an individual has refused to cooperate in the collection of the sample, CSOSA deems the following to be reasonably necessary means for obtaining the sample:

(1) Impose administrative sanctions;

(2) Request a revocation hearing by the releasing authority; and/or

(3) Refer the individual who refuses to cooperate for criminal prosecution for a class A misdemeanor pursuant to section 4(a)(5) of the DNA Analysis Backlog Elimination Act of 2000 (42 U.S.C. 14135b(a)(5)).

APPENDIX A TO PART 812— QUALIFYING DISTRICT OF COLUMBIA CODE OFFENSES

As enacted by the Council of the District of Columbia, the DNA Sample Collection Act of 2001 identifies the criminal offenses listed in Table 1 of this appendix as "qualifying District of Columbia offenses" for the purposes of the DNA Analysis Backlog Elimination Act of 2000 (Pub. L. 106-546, 114 Stat. 2726). Table 2 of this Appendix lists these same offenses in numerical order under the D.C. Code, 1981 Edition. Table 3 of this Appendix lists these same offenses in numerical order under the D.C. Official Code, 2001 Edition. The tables follow:

Table 1. Offense Listing

(1) Section 820 of An Act To establish a code of law for the District of Columbia (arson);

(2) Section 821 of An Act To establish a code of law for the District of Columbia (burning of one's own property with intent to defraud or injure another);

(3) Section 848 of An Act To establish a code of law for the District of Columbia (malicious burning, destruction, or injury of another's property);

(4) Section 803 of An Act To establish a code of law for the District of Columbia (assault with intent to kill, rob, or poison, or to commit first degree sexual abuse, second degree sexual abuse or child sexual abuse);

(5) Section 804 of An Act To establish a code of law for the District of Columbia, (assault with intent to commit mayhem or with dangerous weapon);

(6) Section 806a of An Act To establish a code of law for the District of Columbia (aggravated assault);

(7) Section 432(b) of the Revised Statutes, relating to the District of Columbia (assault on member of police force, campus or university special police, or fire department using a deadly or dangerous weapon);

(8) Section 807 of An Act To establish a code of law for the District of Columbia (mayhem or maliciously disfiguring);

(9) Section 3 of An act for the protection of children in the District of Columbia and for other purposes (cruelty to children);

(10) Section 9 of An Act for the preservation of the public peace and the protection of property within the District of Columbia (lewd, indecent, or obscene acts (knowingly in the presence of a child under the age of 16 years));

(11) Section 823 of An Act To establish a code of law for the District of Columbia (burglary);

(12) Section 875 of An Act To establish a code of law for the District of Columbia (incest);

(13) Section 872 of An Act To establish a code of law for the District of Columbia (certain obscene activities involving minors);

(14) Section 3 of the District of Columbia Protection of Minors Act of 1982 (sexual performances using minors);

(15) Section 812 of An Act To establish a code of law for the District of Columbia (kidnapping);

(16) Section 798 of An Act To establish a code of law for the District of Columbia (murder in the first degree);

(17) Section 799 of An Act To establish a code of law for the District of Columbia (murder in the first degree—obstructing railroad);

(18) Section 800 of An Act To establish a code of law for the District of Columbia (murder in the second degree);

(19) Section 802 of An Act To establish a code of law for the District of Columbia (voluntary manslaughter only);

(20) Section 802a of An Act To establish a code of law for the District of Columbia (murder of a law enforcement officer);

(21) Section 813 of An Act To establish a code of law for the District of Columbia (abducting, enticing, or harboring a child for prostitution);

(22) Section 1 of An Act In relation to pandering, to define and prohibit the same and to provide for the punishment thereof (pandering; inducing or compelling an individual to engage in prostitution);

(23) Section 2 of An Act In relation to pandering, to define and prohibit the same and to provide for the punishment thereof

(compelling an individual to live life of prostitution against his or her will);

(24) Section 4 of An Act In relation to pandering, to define and prohibit the same and to provide for the punishment thereof (causing spouse to live in prostitution);

(25) Section 5 of An Act In relation to pandering, to define and prohibit the same and to provide for the punishment thereof (detaining an individual in disorderly house for debt there contracted);

(26) Forcible rape, carnal knowledge or statutory rape as these offenses were proscribed until May 23, 1995 by section 808 of An Act To establish a code of law for the District of Columbia;

(27) Section 810 of An Act To establish a code of law for the District of Columbia (robbery);

(28) Section 811 of An Act To establish a code of law for the District of Columbia (attempted robbery);

(29) Section 811a of An Act To establish a code of law for the District of Columbia (carjacking);

(30) Indecent acts with children as this offense was proscribed until May 23, 1995 by section 103(a) of An Act To provide for the treatment of sexual psychopaths in the District of Columbia, and for other purposes;

(31) Enticing a child as this offense was proscribed until May 23, 1995 by section 103(b) of An Act To provide for the treatment of sexual psychopaths in the District of Columbia, and for other purposes;

(32) Sodomy as this offense was proscribed until May 23, 1995 by section 104(a) of An Act To provide for the treatment of sexual psychopaths in the District of Columbia, and for other purposes where the offense was forcible or committed against a minor;

(33) Section 201 of the Anti-Sexual Abuse Act of 1994 (first degree sexual abuse);

(34) Section 202 of the Anti-Sexual Abuse Act of 1994 (second degree sexual abuse);

(35) Section 203 of the Anti-Sexual Abuse Act of 1994 (third degree sexual abuse);

(36) Section 204 of the Anti-Sexual Abuse Act of 1994 (fourth degree sexual abuse);

(37) Section 205 of the Anti-Sexual Abuse Act of 1994 (misdemeanor sexual abuse);

(38) Section 207 of the Anti-Sexual Abuse Act of 1994 (first degree child sexual abuse);

(39) Section 208 of the Anti-Sexual Abuse Act of 1994 (second degree child sexual abuse);

(40) Section 209 of the Anti-Sexual Abuse Act of 1994 (enticing a child);

(41) Section 212 of the Anti-Sexual Abuse Act of 1994 (first degree sexual abuse of a ward);

(42) Section 213 of the Anti-Sexual Abuse Act of 1994 (second degree sexual abuse of a ward);

(43) Section 214 of the Anti-Sexual Abuse Act of 1994 (first degree sexual abuse of a patient or client);

(44) Section 215 of the Anti-Sexual Abuse Act of 1994 (second degree sexual abuse of a patient or client);

(45) Section 217 of the Anti-Sexual Abuse Act of 1994 (attempts to commit sexual offenses); and

(46) Attempt or conspiracy to commit any of the offenses listed in items (1) through (45) of this table.

Table 2. Offense Listing (D.C. Official Code, 1981 Edition)

(1) D.C. Code section 22-401—arson;
 (2) D.C. Code section 22-402—burning of one's own property with intent to defraud or injure another;
 (3) D.C. Code section 22-403—malicious burning, destruction or injury of another's property;
 (4) D.C. Code section 22-501—assault with intent to kill, rob, or poison, or to commit first degree sexual abuse, second degree sexual abuse or child sexual abuse;
 (5) D.C. Code section 22-502—assault with intent to commit mayhem or with dangerous weapon;
 (6) D.C. Code section 22-504.1—aggravated assault;
 (7) D.C. Code section 22-505(b)—assault on member of police force, campus or university special police, or fire department using a deadly or dangerous weapon;
 (8) D.C. Code section 22-506—mayhem or maliciously disfiguring;
 (9) D.C. Code section 22-901—cruelty to children;
 (10) D.C. Code section 22-1112(b)—lewd, indecent or obscene acts (knowingly in the presence of a child under the age of 16 years);
 (11) D.C. Code section 22-1801—burglary;
 (12) D.C. Code section 22-1901—incest;
 (13) D.C. Code section 22-2001—certain obscene activities involving a minor;
 (14) D.C. Code section 22-2012—sexual performances using minors;
 (15) D.C. Code section 22-2101—kidnapping;
 (16) D.C. Code section 22-2401—murder in the first degree;
 (17) D.C. Code section 22-2402—murder in the first degree (obstructing railroad);
 (18) D.C. Code section 22-2403—murder in the second degree;
 (19) D.C. Code section 22-2405—voluntary manslaughter only;
 (20) D.C. Code section 22-2406—murder of a law enforcement officer;
 (21) D.C. Code section 22-2704—abducting, enticing, or harboring a child for prostitution;
 (22) D.C. Code section 22-2705—pandering; inducing or compelling an individual to engage in prostitution;
 (23) D.C. Code section 22-2706—compelling an individual to live life of prostitution against his or her will;
 (24) D.C. Code section 22-2708—causing spouse to live in prostitution;
 (25) D.C. Code section 22-2709—detaining an individual in disorderly house for debt there contracted;
 (26) D.C. Code section 22-2801 [repealed May 23, 1995]—forcible rape, carnal knowledge or statutory rape;
 (27) D.C. Code section 22-2901—robbery;
 (28) D.C. Code section 22-2902—attempted robbery;
 (29) D.C. Code section 22-2903—carjacking;
 (30) D.C. Code section 22-3501(a) [repealed May 23, 1995]—indecent acts with children;
 (31) D.C. Code section 22-3501(b) [repealed May 23, 1995]—enticing a child;
 (32) D.C. Code section 22-3502(a) [repealed May 23, 1995]—sodomy where the

offense was forcible or committed against a minor;
 (33) D.C. Code section 22-4102—first degree sexual abuse;
 (34) D.C. Code section 22-4103—second degree sexual abuse;
 (35) D.C. Code section 22-4104—third degree sexual abuse;
 (36) D.C. Code section 22-4105—fourth degree sexual abuse;
 (37) D.C. Code section 22-4106—misdemeanor sexual abuse;
 (38) D.C. Code section 22-4108—first degree child sexual abuse;
 (39) D.C. Code section 22-4109—second degree child sexual abuse;
 (40) D.C. Code section 22-4110—enticing a child;
 (41) D.C. Code section 22-4113—first degree sexual abuse of a ward;
 (42) D.C. Code section 22-4114—second degree sexual abuse of a ward;
 (43) D.C. Code section 22-4115—first degree sexual abuse of a patient or client;
 (44) D.C. Code section 22-4116—second degree sexual abuse of a patient or client;
 (45) D.C. Code section 22-4118—attempts to commit sexual offenses;

(46) Attempt or conspiracy to commit any of the offenses listed in items (1) through (45) of this table.

Table 3. Offense Listing (D.C. Official Code, 2001 Edition)

(1) D.C. Code section 22-301—arson;
 (2) D.C. Code section 22-302—burning of one's own property with intent to defraud or injure another;
 (3) D.C. Code section 22-303—malicious burning, destruction, or injury of another's property;
 (4) D.C. Code section 22-401—assault with intent to kill, rob, or poison, or to commit first degree sexual abuse, second degree sexual abuse or child sexual abuse;
 (5) D.C. Code section 22-402—assault with intent to commit mayhem or with dangerous weapon;
 (6) D.C. Code section 22-404.01—aggravated assault;
 (7) D.C. Code section 22-405(b)—assault on member of police force, campus or university special police, or fire department using a deadly or dangerous weapon;
 (8) D.C. Code section 22-406—mayhem or maliciously disfiguring;
 (9) D.C. Code section 22-801—burglary;
 (10) D.C. Code section 22-1101—cruelty to children;
 (11) D.C. Code section 22-1312(b)—lewd, indecent, or obscene acts (knowingly in the presence of a child under the age of 16 years);
 (12) D.C. Code section 22-1901—incest;
 (13) D.C. Code section 22-2001—kidnapping;
 (14) D.C. Code section 22-2101—murder in the first degree;
 (15) D.C. Code section 22-2102—murder in the first degree—obstructing railroad;
 (16) D.C. Code section 22-2103—murder in the second degree;
 (17) D.C. Code section 22-2105—voluntary manslaughter only;
 (18) D.C. Code section 22-2106—murder of a law enforcement officer;
 (19) D.C. Code section 22-2201—certain obscene activities involving minors;

(20) D.C. Code section 22-2704—abducting, enticing, or harboring a child for prostitution;
 (21) D.C. Code section 22-2705—pandering; inducing or compelling an individual to engage in prostitution;
 (22) D.C. Code section 22-2706—compelling an individual to live life of prostitution against his or her will;
 (23) D.C. Code section 22-2708—causing spouse to live in prostitution;
 (24) D.C. Code section 22-2709—detaining an individual in disorderly house for debt there contracted;
 (25) D.C. Code section 22-2801—robbery;
 (26) D.C. Code section 22-2802—attempted robbery;
 (27) D.C. Code section 22-2803—carjacking;
 (28) D.C. Code section 22-3002—first degree sexual abuse;
 (29) D.C. Code section 22-3003—second degree sexual abuse;
 (30) D.C. Code section 22-3004—third degree sexual abuse;
 (31) D.C. Code section 22-3005—fourth degree sexual abuse;
 (32) D.C. Code section 22-3006—misdemeanor sexual abuse;
 (33) D.C. Code section 22-3008—first degree child sexual abuse;
 (34) D.C. Code section 22-3009—second degree child sexual abuse;
 (35) D.C. Code section 22-3010—enticing a child;
 (36) D.C. Code section 22-3013—first degree sexual abuse of a ward;
 (37) D.C. Code section 22-3014—second degree sexual abuse of a ward;
 (38) D.C. Code section 22-3015—first degree sexual abuse of a patient or client;
 (39) D.C. Code section 22-3016—second degree sexual abuse of a patient or client;
 (40) D.C. Code section 22-3018—attempts to commit sexual offenses;
 (41) D.C. Code section 22-3102—sexual performances using minors;
 (42) D.C. Code section 22-3801(a) [repealed May 23, 1995]—indecent acts with children;
 (43) D.C. Code section 22-3801(b) [repealed May 23, 1995]—enticing a child;
 (44) D.C. Code section 22-3802(a) [repealed May 23, 1995]—sodomy where the offense was forcible or committed against a minor;
 (45) D.C. Code section 22-4801 [repealed May 23, 1995]—forcible rape, carnal knowledge or statutory rape;
 (46) D.C. Code section 22-1803 or section 22-1805a—attempt or conspiracy to commit any of the offenses listed in items (1) through (45) of this table.

[FR Doc. 02-20606 Filed 8-20-02; 8:45 am]

BILLING CODE 3129-01-P

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****29 CFR Part 1926****[Docket No. S204A]****RIN 1218-AC02****Regulatory Flexibility Act Review of the Excavations Standard**

AGENCY: Occupational Safety and Health Administration, U.S. Department of Labor.

ACTION: Regulatory Flexibility Act review; request for comments.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is conducting a review of the Excavations Standard pursuant to Section 610 of the Regulatory Flexibility Act and Section 5 of Executive Order 12866 on Regulatory Planning and Review. The purpose of this review is to determine, while protecting worker safety, whether this standard should be maintained without change, rescinded, or modified in order to minimize any significant impact of the rule on a substantial number of small entities and whether the rule should be changed to reduce regulatory burden or improve its effectiveness. Written public comments on these and other relevant issues are welcomed.

DATES: Written comments to OSHA must be sent or postmarked by November 19, 2002.

ADDRESSES: You may submit three copies of your written comments to the OSHA Docket Office, Docket No. S204A, Technical Data Center, Room N-2625, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone (202) 693-2350. If your written comments are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693-1648. You do not have to send OSHA a hard copy of your faxed comments.

You may submit comments electronically through OSHA's Homepage at <http://ecomments.osha.gov/>. Please note that you may not attach materials such as studies or journal articles to your electronic comments. If you wish to include such materials, you must submit three copies of the material to the OSHA Docket Office at the above address. When submitting such materials to the OSHA Docket Office, you must clearly identify your electronic comments by name, date, subject, and docket number so that we can attach them to your electronic comments.

FOR FURTHER INFORMATION CONTACT:

Joanna Dizikes Friedrich, Directorate of Policy, Occupational Safety and Health Administration, Room N3641, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 693-2400, Fax (202) 693-1641.

SUPPLEMENTARY INFORMATION: In 1971, the Secretary of Labor promulgated a safety standard for excavations (36 FR 7340, April 17, 1971) pursuant to section 107 of the Contract Work Hours and Safety Standards Act. Later in 1971, OSHA designated this Standard as an established occupational safety and health standard (36 FR 10466, May 29, 1971) in accordance with section 6(a) of the Occupational Safety and Health Act.

In 1989, OSHA revised this Standard (54 FR 45894, October 31, 1989) to use performance criteria where possible, rather than specification requirements; to consolidate and simplify existing provisions; to add and clarify definitions; to eliminate duplicate provisions and ambiguous language; to provide a consistent method of soil classification; and to give employers added flexibility in providing protection for employees. The Standard was amended August 9, 1994 (59 FR 40730) to protect workers using walkways over excavations.

The Excavations Standard is currently found in 29 CFR, subpart P, 1926.650-1926.652 and Appendices A-F, and covers the construction industry. The purpose of the Standard is to protect employees from deaths and injuries resulting from excavation work, including deaths and injuries resulting from cave-ins. The Standard regulates the use of support systems, sloping and benching systems, and other systems of protection as means of protection against excavation cave-ins. In addition, the Standard regulates the means of access to and egress from excavations, along with employee exposure to vehicular traffic, falling loads, hazardous atmospheres, water accumulation, and unstable structures in and adjacent to excavations. The Standard applies to all types of excavations, including trenches, made in the earth's surface.

OSHA has selected the Excavation Standard for review in accordance with the regulatory review provisions of Section 610 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and Section 5 of Executive Order 12866 (58 FR 51735, 51739, October 4, 1993). The purpose of a review under Section 610 of the Regulatory Flexibility Act:

(S)hall be to determine whether such rule should be continued without change, or should be rescinded, or amended consistent

with the stated objectives of applicable statutes to minimize any significant impact of the rules on a substantial number of small entities.

The Agency shall consider the following factors:

- (1) The continued need for the rule;
- (2) The nature of complaints or comments received concerning the rule from the public;
- (3) The complexity of the rule;
- (4) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and
- (5) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

The review requirements of Section 5 of Executive Order 12866 require agencies:

To reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the [Agency] have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive Order, within applicable law; and to otherwise improve the effectiveness of existing regulations.

An important step in the review process involves the gathering and analysis of information from affected persons about their experience with the rule and any material changes in circumstances since issuance of the rule. This document requests written comments on the continuing need for the rule, its adequacy or inadequacy, its small business impacts, and other relevant issues. Comments concerning the following subjects would assist the Agency in its review. (The purpose of these questions is to assist commenters in their responses and not to limit the format or substance of their comments. Of course, comments are requested on all issues raised by Section 610 of the Regulatory Flexibility Act and Section 5 of Executive Order 12866.)

Safety/Effectiveness

1. Do any aspects of Subpart P need to be updated as a result of technological developments over the past decade?

2. Does compliance with the Excavations Standard at 29 CFR subpart P (i.e., §§ 1926.650-1926.652 and Appendices A-E) provide safety from cave-ins and other trenching and excavation accidents? Are there additional protections which could improve safety?

3. If firms fail to comply with the Excavations Standard, is non-compliance more commonly the result of: (1) A lack of information (e.g., about the dangers, or the safety requirements); (2) inadequate supervision; (3) cost pressures; or (4) other factors? How could OSHA encourage improved compliance?

4. Are OSHA's requirements in the Excavations Standard known to firms that do trenching and excavation jobs, including small firms and firms that dig trenches only occasionally? How could awareness be increased for such firms?

Costs and Impacts

5. Does OSHA's Excavations Standard impose an unnecessary burden to small businesses, or to industry in general? If so, which requirements, and how could this burden be reduced without decreasing safety?

6. Do any of the requirements in the Excavations Standard lead to a disproportionate burden on small entities? If so, which requirements lead to a disproportionate burden, and how?

7. What percent of the time and cost of an excavation job do safety measures represent? Do these percentages vary significantly depending on the type of job, soil, firm, or other factors? Provide data, if possible.

8. Which types of safety measures have the greatest impact on productivity? The lowest impact on productivity?

9. Do bidding practices (or requirements) for construction jobs encourage or discourage uniform compliance with the Excavations Standard (e.g., by explicitly identifying planned subpart P safety measures in bids delivered to customers, or by certifying compliance with subpart P as part of the bid)?

10. How have changes in technology, the economy, or other factors affected the compliance costs associated with the rule over the past decade or so?

11. How might OSHA modify the requirements to reduce costs without jeopardizing safety?

Clarity/Duplication

12. Are any aspects of the Excavations Standard unclear, needlessly complex, or duplicative? Do any portions of the Excavations Standard overlap, duplicate, or conflict with other Federal, State or local government rules?

13. Do other government entities, including other countries, have alternative trenching and excavation approaches? If so, how do they differ from OSHA's approach? Are these alternative approaches more effective?

Additional Information on the Excavations Standard: The major occupational hazards of excavation work result from cave-ins, from exposure to underground utilities, and from material or equipment falling into the excavation. Precautions to protect against cave-ins include bracing, sloping, benching, and shielding. However, the proper use of these techniques requires an understanding of the importance of such factors as excavation depth and width, soil type, hydraulic pressure, and other specific conditions present at the worksite.

Excavation work is performed during the construction of buildings, bridges, towers, and other construction projects. There is a greater economic incentive to shore excavations, as opposed to trenches, due to the greater risks of incurring re-excavation expenses due to collapsed walls, and due to the possibility that damage suits would result from the collapse of buildings located adjacent to an excavation. In comparison, trenching is primarily performed by utility contractors who construct gas, sewer, water, and utility lines. Much of this work is performed as a result of competitive bids from state and local governments or local utilities. Trenches are less likely to be in close proximity to other structures; structures adjacent to trenches are less likely to collapse; and the cost of redigging a collapsed trench is far less than of re-excavating the foundation of a building.

OSHA statistics show that during the period 1990–2000, an average of approximately 70 fatalities per year occurred as a result of excavation and trenching accidents. These fatalities fall across numerous Standard Industrial Classifications (SICs),¹ but over 80 percent of the fatalities occurred in the following 12 SICs:

SIC 1623—Water, sewer, pipeline, communications, and power line
SIC 1794—Excavation work
SIC 1711—Plumbing, heating, and air conditioning
SIC 1629—Heavy construction
SIC 1542—General contractors, non-residential, non-industrial
SIC 1611—Highway and street construction
SIC 1521—General contractors, single family homes
SIC 1771—Concrete work
SIC 1799—Special trade contractors

¹ Industries are classified by SIC, as opposed to the newer North American Industrial Classification (NAIC) system, due to the historical nature of OSHA's statistics. The relevant NAICs fall within NAIC 23 (Construction), including NAIC 233 (Building, Developing, and General Contracting), 234 (Heavy Construction), 235 (Special Trade Contractors), and other subclassifications.

SIC 1622—Bridge, tunnel, and elevated highway

SIC 1731—Electrical work

SIC 1795—Wrecking and demolition work

While the annual number of fatalities has remained fairly constant over this 1990–2000 period, the fatality rate as a percentage of the real value of construction activity has declined. One factor contributing to this decline has been an increased use of new “trenchless” technologies, such as directional drilling, pipejacking, microtunnelling, auger boring, impact ramming, pipe bursting, folded pipes, and spray on linings. These technologies can result in fewer accidents by eliminating or reducing the amount of time that workers are physically exposed to the hazards of trenching. For example, some of these technologies use remote-controlled equipment to dig and lay cables, to install pipe, or to replace existing pipes.

The construction industry has grown by approximately 20 percent (constant dollars) since the Excavations Standard was last modified in 1989. The Small Business Administration (SBA) generally classifies the entities affected by this standard as small if their annual revenues are less than \$12 million (for affected entities falling within NAIC 235) or \$28.5 million (for affected entities falling within NAICs 233 and 234). Under these guidelines, the vast majority of entities affected by the Standard are small entities.

Comments: All comments shall be submitted or postmarked by November 19, 2002, to the address above. OSHA will review the written public comments as part of the process of conducting this regulatory review of the Excavations Standard. All comments received will be included in Docket No. S204A and will be available for public review in the OSHA Docket Office.

Authority: This document was prepared under the direction of John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, on August 14, 2002.

John L. Henshaw,

Assistant Secretary.

[FR Doc. 02–21221 Filed 8–20–02; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 100****[CGD05–02–057]****RIN 2115–AE46****Special Local Regulations for Marine Events; Bush River, Abingdon, Maryland****AGENCY:** Coast Guard, DOT.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations during the “Harford County Power Boat Regatta”, a marine event to be held on the waters of Bush River near Abingdon, Maryland. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Bush River during the event.

DATES: This rule is effective from 11:30 a.m. on August 31, 2002 to 6:30 p.m. on September 1, 2002.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD05–02–057 and are available for inspection or copying at Commander (Aoax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004, between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ronald Houck, Marine Information Specialist, Commander, Coast Guard Activities Baltimore, at (410) 576–2674.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. In keeping with 5 U.S.C. 553(b)(B) and 553(d)(3), the Coast Guard finds that good cause exists for not publishing a NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**. The event will begin on Saturday, August 31, 2002. There is not sufficient time to allow for a notice and comment period, prior to the event. Because of the danger inherent in high-speed boat races, special local regulations are necessary to provide for the safety of participants, spectator craft and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event. In addition, advance notifications will be made via

the Local Notice to Mariners, marine information broadcasts, and area newspapers.

Background and Purpose

On August 31 and September 1, 2002, the Harford County Power Boat Association will sponsor the “Harford County Power Boat Regatta”, on the waters of the Bush River, near Abingdon, Maryland. The event will consist of approximately 75 inboard hydroplanes and runabouts racing in heats counter-clockwise around a 1.25-mile oval racecourse. A fleet of spectator vessels is anticipated. Due to the need for vessel control during the races, vessel traffic will be temporarily restricted to provide for the safety of spectators, participants and transiting vessels.

Discussion of Rule

The Coast Guard is establishing temporary special local regulations on specified waters of the Bush River. The temporary special local regulations will be enforced from 11:30 a.m. to 6:30 p.m. on both August 31 and September 1, 2002. The effect will be to restrict general navigation in the regulated area during the event. Except for participants in the “Harford County Power Boat Regatta” and vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area. The Patrol Commander will allow non-participating vessels to transit the event area between races at slow speed. These regulations are needed to control vessel traffic during the event to enhance the safety of participants, spectators and transiting vessels.

Regulatory Evaluation

This rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not “significant” under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

Although this rule prevents traffic from transiting a portion of the Bush River during the event, the effect of this rule will not be significant due to the limited duration of the regulation, the fact that the Patrol Commander will allow non-participating vessels to transit the event area between races, and the extensive advance notifications that will be made to the maritime community via the Local Notice to

Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in the effected portions of the Bush River during the event.

Although this rule prevents traffic from transiting or anchoring in a portion of the Bush River during the event, the effect of this rule will not be significant because of its limited duration, the fact that the Patrol Commander will allow non-participating vessels to transit the event area between races, and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this temporary rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the address listed under **ADDRESSES**.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by

employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial and direct effect on one or more Indian tribes, on the relationship between the

Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that Order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We prepared an "Environmental Assessment" in accordance with Commandant Instruction M16475.1C, and determined that this rule will not significantly affect the quality of the human environment. The "Environmental Assessment" and "Finding of No Significant Impact" is available in the docket where indicated under ADDRESSES.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46.

2. From 11:30 a.m. on August 31, 2002 to 6:30 p.m. on September 1, 2002, add temporary section, § 100.35-T05-057 to read as follows:

§ 100.35-T05-057 Bush River, Abingdon, Maryland.

(a) *Definitions.*

(1) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Activities Baltimore.

(2) *Official Patrol.* The Official Patrol is any vessel assigned or approved by Commander, Coast Guard Activities Baltimore with a commissioned,

warrant, or petty officer on board and displaying a Coast Guard ensign.

(3) *Participant.* Includes all vessels participating in the Harford County Power Boat Regatta under the auspices of the Marine Event Permit issued to the event sponsor and approved by Commander, Coast Guard Activities Baltimore.

(b) *Regulated area.* Includes the waters of the Bush River bounded on the south by the Amtrak railroad drawbridge, thence northerly from the eastern end of the drawbridge along the shoreline to Church Point at latitude 39°27'48" N, longitude 76°13'42" W, thence westerly to Bush Point at latitude 39°27'42" N, longitude 76°14'30" W, thence southwesterly along the shoreline to Otter Point at latitude 39°26'48" N, longitude 76°15'42" W, thence southerly to Flying Point at latitude 39°26'30" N, longitude 76°15'30" W, thence southeasterly along the shoreline to the western end of the Amtrak railroad drawbridge. All coordinates reference Datum: NAD 1983.

(c) *Special local regulations.*

(1) Except for event participants and persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in the regulated area shall:

(i) Stop the vessel immediately when directed to do so by any official patrol.

(ii) Proceed as directed by any official patrol.

(iii) Unless otherwise directed by the official patrol, operate at a minimum wake speed not to exceed six (6) knots.

(d) *Enforcement period.* This section will be enforced from 11:30 a.m. to 6:30 p.m. on both August 31 and September 1, 2002.

Dated: August 14, 2002.

A.E. Brooks,

Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 02-21298 Filed 8-20-02; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Francisco 02-017]

RIN 2115-AA97

Safety Zone; San Francisco Bay, CA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing moving safety zones extending one-hundred (100) yards around each vessel participating in the Parade of Ships-Festival of Sail as each vessel transits through San Francisco Bay to its respective mooring site on August 28, 2002. These temporary safety zones are necessary to provide for the safety of the crews, spectators, participants of the event, participating vessels and other vessels and users of the waterway. Persons and vessels are prohibited from entering into, transiting through, or anchoring within these safety zones unless authorized by the Captain of the Port, or his designated representative.

DATES: This rule is effective from 12 [PDT] to 4:30 [PDT] on August 28, 2002.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket [COTP San Francisco 02-017] and are available for inspection or copying at U.S. Coast Guard Marine Safety Office San Francisco Bay, Coast Guard Island, Building 14, Alameda, CA 94501-5100, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Diana Cranston, Chief, Waterways Management Branch, U.S. Coast Guard Marine Safety Office San Francisco Bay, at (510) 437-3073.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Final approval and permitting of this event were not issued in time to engage in notice and comment rulemaking. Moreover, through various meetings and correspondence, the Coast Guard has attempted to involve other agencies in the planning process of the Parade of Ships-Festival of Sail. The public will also be reminded about this event through Broadcast Notice to Mariners (BNM) announcements and Local Notice to Mariner (LNM) publications. Moreover, the event will have minimal impact on the public since it is of a short duration, four and one-half (4.5) hours, and will take place during non-commute hours from 12 p.m. until 4:30 p.m.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. It would be contrary to the public interest not to publish this rule because the event has been permitted

and participants and the public require protection.

Background and Purpose

The American Sail Training Association, in coordination with local sponsors like "Sail San Francisco", is sponsoring the 2002 Tall Ships Challenge race series transiting the Pacific Ocean along the west coast of North America. Between the races, the participating vessels will visit several ports including San Francisco Bay. These temporary safety zones are established in support of the Parade of Ships-Festival of Sail, a marine event that includes participating vessels transiting through San Francisco Bay and, upon completion of the parade, mooring in San Francisco Bay, giving spectators an opportunity to tour the participating vessels. These temporary safety zones are necessary to provide for the safety of the crews, spectators, and participants of the Parade of Ships-Festival of Sail and are also necessary to protect other vessels and users of waterway.

Discussion of Rule

The Coast Guard establishes moving safety zones extending one-hundred (100) yards around each vessel participating in the Parade of Ships-Festival of Sail as each vessel transits through San Francisco Bay to its respective mooring site. Vessels participating in the event will fly a black-and-yellow pennant indicating their official association with the Parade of Ships-Festival of Sail. The safety zones surrounding the participant vessels will be enforced from 12 p.m. to 4:30 p.m. on August 28, 2002. The safety zones are necessary to provide for the safety of the crews, spectators, and participants of the Parade of Ships-Festival of Sail and to protect other vessels and users of the waterways. Persons and vessels would be prohibited from entering into, transiting through, or anchoring within these safety zones unless authorized by the Captain of the Port, or his designated representative.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary because of its limited duration of four and one-half (4.5) hours and the limited geographic scope of the safety zones.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

These safety zones would not have a significant economic impact on a substantial number of small entities because these zones are limited in scope and duration (in effect for only four and one-half (4.5) hours on August 28, 2002). In addition, the Coast Guard will issue broadcast notice to mariners alerts via VHF-FM marine channel 16 before the safety zone is enforced.

Assistance for Small Entities

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have

determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that Order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the

Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph (34)(g), of Commandant Instruction M16475.1D, this rule is categorically excluded from further environmental documentation because we are proposing to establish a safety zone. A “Categorical Exclusion Determination” is available in the docket where indicated under ADDRESSES.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. Add a new § 165.T11–089 to read as follows:

§ 165.T11–089 Safety Zone; San Francisco Bay, CA.

(a) *Location.* Temporary moving safety zones are established as a one-hundred (100) yard radius around each vessel participating in the Parade of Ships-Festival of Sail as each vessel transits through San Francisco Bay to its respective mooring site. The vessels participating in this event will be distinguished by their flying a black and yellow pennant.

(b) *Effective period.* This section is effective from 12:00 p.m. until 4:30 p.m. on August 28, 2002.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through or anchoring within these safety zones is prohibited unless authorized by the Coast Guard Captain of the Port, San Francisco, or his designated representative.

Dated: August 12, 2002.

L. L. Hereth,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco Bay, California.

[FR Doc. 02–21297 Filed 8–20–02; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0150; FRL–7188–4]

Imidacloprid; Re-Establishment of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes time-limited tolerances for combined residues of the insecticide imidacloprid (1-[6-chloro-3-pyridinyl] methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine, in or on turnip, roots at 0.3 parts per million (ppm); turnip, tops at 3.5 ppm; beet, garden, roots at 0.3 ppm; and beet, garden, tops for an additional 2-year period. These tolerances will expire and are revoked on June 30, 2004. This action is in response to EPA’s granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on turnips and garden beets. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation is effective August 21, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0150, must be received on or before October 21, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0150 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9367; e-mail address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0150. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in

those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA issued a final rule, published in the **Federal Register** of November 29, 1996 (FRL-5575-1), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170), it established time-limited tolerances for the combined residues of the insecticide imidacloprid (1-[6-chloro-3-pyridinyl] methyl]-N-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine, in or on turnip roots at 0.3 ppm; turnip tops at 3.5 ppm; beet roots at 0.3 ppm; and beet tops at 3.5 ppm with an expiration date of November 29, 1997.

These tolerances were subsequently extended on in **Federal Register** documents published on December 12, 1997 (extended to November 29, 1998), October 7, 1998 (extended to June 30, 2000), and August 9, 2000 (extended to June 30, 2002). The extension that was published on August 9, 2000 amended § 180.472(b) by extending the expirations dates of turnip roots; turnip tops; beet roots; and beet tops. However, these changes have never been reflected in the tolerance table in § 180.472(b) because the time-limited tolerances for these commodities were originally listed in the tolerance table for § 180.472(a). This document will re-establish the tolerances using the correct commodity terms from the Food and Feed Commodity Vocabulary database, correctly place them in the table to § 180.472(b), and remove the commodities turnip roots, turnip tops, beet roots and beet tops from the table in § 180.472(a).

Recently, EPA has received an objection to a tolerance it established for imidacloprid on a different food commodity. The objection was filed by the Natural Resources Defense Council (NRDC) and raised several issues

regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. Although this objection concerns separate rulemaking proceedings under the FFDCA, EPA has considered whether it is appropriate to re-establish the emergency exemption tolerances for imidacloprid while the objection is still pending.

Factors taken into account by EPA included how close the Agency is to concluding the proceedings on the objection, the nature of the current action, whether NRDC's objection raised frivolous issues, and the extent to which the issues raised by NRDC had already been considered by EPA. Although NRDC's objection is not frivolous, the other factors all support extending these tolerances at this time. First, the objections proceeding is not near to conclusion. NRDC's objections raise complex legal, scientific, policy, and factual matters and EPA has just initiated a 60 day public comment period on them. (See 67 FR 41628, June 19, 2002, FRL-7167-7) Second, the nature of the current actions are extremely time-sensitive as they address emergency situations. Third, the issues raised by NRDC are not new matters but questions that have been the subject of considerable study by EPA and comment by stakeholders. Accordingly, EPA is proceeding with re-establishing the tolerances for imidacloprid.

EPA established the tolerances because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of imidacloprid on turnips and garden beets for this year's growing season due to a continuation of the emergencies in California and Arizona. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of imidacloprid on turnips and garden beets for control of aphids in Arizona and California, respectively.

EPA assessed the potential risks presented by residues of imidacloprid in or on turnip roots, turnip tops, garden beet roots, and garden beet tops. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerances under FFDCA section

408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule published in the **Federal Register** of November 29, 1996 (FRL-5575-1). Based on that data and information considered, the Agency reaffirms that re-establishment of the time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are re-established for an additional 2-year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR). Although these tolerances will expire and are revoked on June 30, 2004, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on turnip, roots; turnip, tops; beet, garden, roots; and beet, garden, tops after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerances. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA,

you must identify docket ID number OPP-2002-0150 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 21, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit III.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP-2002-0150, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Regulatory Assessment Requirements

This final rule re-establishes time-limited tolerances under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to

Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not

alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 11, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. In § 180.472, amend the table in paragraph (a) by removing the entries for the commodities turnip tops; turnip roots; beet tops; and beet roots and amend the table in paragraph (b) by adding alphabetically the following entries:

§ 180.472 Imidacloprid; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
Beet, garden, roots;	0.3	06/30/04
Beet, garden, tops;	3.5	06/30/04
* * *	*	*
Turnip, roots;	0.3	06/30/04
Turnip, tops;	3.5	06/30/04
* * *	*	*

* * * * *

[FR Doc. 02-20990 Filed 8-20-02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2002-0176; FRL-7191-5]

Sulfentrazone; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of sulfentrazone, N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide, and its metabolites 3-hydroxymethyl sulfentrazone (HMS) and 3-desmethyl sulfentrazone (DMS) in or on flax, seed; potato; potato, wet peel; and potato, granules/flakes. This action is in response to EPA's granting of an emergency exemption under section 18

of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on flax and potatoes. This regulation establishes maximum permissible levels for residues of sulfentrazone in these food commodities. These tolerances will expire and are revoked on December 31, 2004.

DATES: This regulation is effective August 21, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0176, must be received on or before October 21, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number -OPP-2002-0176 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9367; e-mail address: Ertman.Andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person

listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml/00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0176. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the herbicide sulfentrazone, N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide, and its metabolites 3-hydroxymethyl sulfentrazone (HMS) and 3-desmethyl sulfentrazone (DMS), in or on flax, seed at 0.20 part per million (ppm); potato at

0.10 ppm; potato, wet peel at 0.15 ppm; and potato, granules/flakes at 0.20 ppm. These tolerances will expire and are revoked on December 31, 2004. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Sulfentrazone on Flax and Potatoes and FFDCA Tolerances

North Dakota submitted a section 18 request for the emergency use of sulfentrazone on flax to control kochia. EPA reviewed this request and concluded that the situation was urgent and non-routine.

Colorado and Nebraska submitted section 18 requests for the emergency use of sulfentrazone on potatoes to control ALS-inhibitor and triazine-resistant Palmer amaranth, redroot pigweed, common waterhemp. EPA reviewed these requests and concluded that the situations were urgent and non-routine. EPA has authorized under FIFRA section 18 the use of sulfentrazone on flax to control kochia in North Dakota, and on potatoes for control of ALS-inhibitor and triazine-resistant Palmer amaranth, redroot pigweed, common waterhemp in Colorado and Nebraska. After having reviewed these submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of sulfentrazone in or on flax and potatoes. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2004, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on flax, seed; potato; potato, wet peel; potato, granules/flakes after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether sulfentrazone meets EPA's registration requirements for use on flax and/or potatoes or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of sulfentrazone by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than North Dakota, Colorado and Nebraska to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for sulfentrazone, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of sulfentrazone and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of sulfentrazone in or on flax, seed at 0.20 ppm; potato at 0.10 ppm; potato, wet peel at 0.15 ppm; and potato, granules/flakes at 0.20 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study

selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF ($RfD = NOAEL / UF$). Where an additional safety factor is retained due to concerns unique to FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = $NOAEL / \text{exposure}$) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{\text{cancer}} = \text{point of departure} / \text{exposures}$) is calculated. A summary of the toxicological endpoints for sulfentrazone used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SULFENTRAZONE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13–50 years of age	NOAEL = 10.0 mg/kg/day UF = 100 Acute RfD = 0.10 mg/kg/day	FQPA SF = 10 aPAD = acute RfD ÷ FQPA SF = 0.01 mg/kg/day	Developmental study in rats Developmental LOAEL = 25 mg/kg/day based on decreased fetal weight and retarded skeletal development as evidenced by an increased number of litters with any variation and by decreased numbers of caudal vertebral and metacarpal ossification sites.
Acute dietary general population including infants and children	NOAEL = 250 mg/kg/day UF = 100 Acute RfD = 2.5 mg/kg/day	FQPA SF = 10 aPAD = acute RfD ÷ FQPA SF = 0.25 mg/kg/day	Acute neurotoxicity study in rats LOAEL = 750 mg/kg/day based on increased incidences of clinical signs abdominal gripping, abdominogenital staining, and/or red-dish-brown staining under the cage, FOB findings, and decreased motor activity which were reversed by day 14 post dose.
Chronic dietary all populations	NOAEL = 14.0 mg/kg/day UF = 100 Chronic RfD = 0.14 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD ÷ FQPA SF = 0.014 mg/kg/day	2-generation reproduction study in rats LOAEL = 33/44 mg/kg/day in males and females, respectively, based on 1) decreased maternal body weight and/or body weight gain during gestation in both P and F1 generations, 2) reduced prenatally body weight gains in the second generation (F1 adults), 3) increased duration of gestation in both F1 and F2 dams, 4) reduced prenatal viability (fetal and litter), 5) reduced litter size, 6) increased number of stillborn pups, 7) reduced pup and litter postnatal survival, and 8) decreased pup body weights throughout gestation. In males, effects included decreased fertility in F1 generation and/or atrophy of the germinal epithelium of the testes, oligospermia and intratubular degeneration of the seminal product in the epididymis.

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.498) for the combined residues of sulfentrazone, in or on a variety of raw agricultural commodities. A permanent tolerance has been established for residues of sulfentrazone on soybean seed. Tolerances are established for inadvertent and indirect residues of sulfentrazone on cereal grains. Time-limited tolerances have been established on bean, lima (succulent seed without pod); cowpeas (without pod); horseradish, roots; sugarcane, cane; sunflower, seeds; and, sunflower, forage. These time-limited tolerances have an expiration date of 12/31/02. Risk assessments were conducted by EPA to assess dietary exposures from sulfentrazone in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day

or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues and 100% crop treated information were used for all commodities (Tier 1). As the acute analyses were Tier 1 assessments, acute risk estimates are presented at the 95th percentile.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level

residues and 100% crop treated information were used for all commodities (Tier 1).

iii. *Cancer.* Sulfentrazone has been classified as a “Group E” chemical (not likely to be carcinogenic to humans via relevant routes of exposure). Therefore, no cancer risk assessment was performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for sulfentrazone in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of sulfentrazone.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide

concentrations in surface water and screening concentration in ground water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to sulfentrazone they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of sulfentrazone for acute exposures are estimated to be 16 parts per billion (ppb) for surface water and 16 ppb for ground water. The EECs for chronic exposures are estimated to be 4 ppb for surface water and 16 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Sulfentrazone is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether sulfentrazone has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, sulfentrazone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfentrazone has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies—i. Rats.* In the oral developmental study in rats, the maternal (systemic) NOAEL was 25 mg/kg/day, based on increased spleen weights and splenic extramedullary hematopoiesis at the LOAEL of 50 mg/kg/day. The developmental (fetal) NOAEL was 10 mg/kg/day, based on decreased mean fetal weight and retardation in skeletal development as evidenced by increased numbers of litters with any variation and by decreased numbers of caudal vertebral and metacarpal ossification sites at the LOAEL of 25 mg/kg/day.

In the dermal developmental study in rats, the maternal (systemic) NOAEL was 250 mg/kg/day and a LOAEL was not determined. The developmental (fetal) NOAEL was 100 mg/kg/day, based on decreased fetal weight and increased fetal variations (hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, incompletely ossified ischia or pubes, and reduced numbers of thoracic vertebral and rib ossification sites) at the LOAEL of 250 mg/kg/day.

ii. *Rabbits.* In the oral developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 100 mg/kg/day, based on increased abortions, clinical signs (decreased feces and hematuria), and reduced body weight gain during gestation at the LOAEL of 250 mg/kg/day. The developmental (pup) NOAEL was 100 mg/kg/day, based on increased resorptions, decreased live fetuses per litter, and decreased fetal weight at the LOAEL of 250 mg/kg/day.

3. *Reproductive toxicity study—Rats.* In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOAEL was 14/16 mg/kg/day in males and females, respectively, based on decreased maternal body weight and/or body weight gain during gestation in both P and F1 generations, and reduced prenatally body weight gains in the second generation (F1 adults) at the LOAEL of 33/44 mg/kg/day for males and females, respectively. The developmental (pup) NOAEL was 14/16 mg/kg/day based on: (1) Reduced prenatal viability (fetal and litter), (2) reduced litter size, (3) increased number of stillborn pups, (4) reduced pup and litter postnatal survival, and (5) decreased pup body weights throughout lactation at the LOAEL of 33/44 mg/kg/day. The reproductive NOAEL was 14/16 mg/kg/day, based on: (1) Increased duration of gestation in both F1 and F2 dams, (2) decreased fertility in F1 generation (males), and/or (3) atrophy of the germinal epithelium of the testes, oligospermia and intratubular degeneration of the seminal product in the epididymis at the LOAEL of 33/44 mg/kg/day.

4. *Prenatal and postnatal sensitivity.* The toxicological database for evaluating prenatal and postnatal toxicity for sulfentrazone is complete with respect to current data requirements. Based on the developmental and reproductive toxicity studies discussed above for sulfentrazone there appears to be prenatal and postnatal sensitivity.

5. *Conclusion.* There is a complete toxicity database for sulfentrazone and exposure data are complete or are estimated based on data that reasonably

accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be retained. For acute dietary analysis, the FQPA safety factor was retained and is applicable to the U.S. population and all subgroups due to the increased susceptibility observed in the prenatal developmental studies. For chronic dietary analysis, the FQPA safety factor was retained and is applicable for all populations due to the qualitative increased susceptibility observed in the 2-generation reproduction study.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is

available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to sulfentrazone in drinking water (when considered along with other sources of exposure for which EPA has

reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of sulfentrazone on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to sulfentrazone will occupy <1% of the aPAD for the U.S. population, 8% of the aPAD for females 13 years and older, <1% of the aPAD for all infants (<1 year old) and <1% of the aPAD for children (1–6 years old). In addition, despite the potential for acute dietary exposure to sulfentrazone in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of sulfentrazone in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO SULFENTRAZONE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females, 13–50 years old	0.01	8	16	16	270
U.S. Population	0.25	<1	16	16	8,700
Children (1–6 years old) and all infants (<1 year old)	0.25	<1	16	16	2500

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sulfentrazone from food will utilize 3% of the cPAD for the U.S. population, 5% of the cPAD for all infants (<1 year old) and 6% of the

cPAD for children (1–6 years old). There are no residential uses for sulfentrazone that result in chronic residential exposure to sulfentrazone. In addition, despite the potential for chronic dietary exposure to sulfentrazone in drinking water, after calculating DWLOCs and

comparing them to conservative model EECs of sulfentrazone in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO SULFENTRAZONE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.014	4	4.0	16	470
Children (1–6 years old) and all infants (< 1 year old)	0.014	8	4.0	16	130
Females (13–50 years old)	0.014	3	4.0	16	410
Males (13–19 years old)	0.014	4	4.0	16	470

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Sulfentrazone is not registered for use

on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

Sulfentrazone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population.* Because sulfentrazone is not a carcinogen, a cancer aggregate risk assessment was not conducted.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to sulfentrazone residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical methodology for the determination of sulfentrazone, 3-desmethyl sulfentrazone, and 3-hydroxymethyl sulfentrazone residues in/on various matrices was submitted with a petition for a sulfentrazone tolerance on soybeans. A petition method validation (PMV) was successfully completed by the Agency's Analytical Chemistry Laboratory. The Limit of Quantitation (LOQ) and Minimum Detection Limit (MDL) were determined to be 0.05 ppm and 0.005–0.025 ppm, respectively. EPA concluded that the method is suitable for enforcement purposes.

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex maximum residue limits (MRLs) established for sulfentrazone on either flax or potatoes.

VI. Conclusion

Therefore, the tolerances are established for combined residues of sulfentrazone, N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide, and its metabolites 3-hydroxymethyl sulfentrazone (HMS) and 3-desmethyl sulfentrazone (DMS), in or on flax, seed at 0.20 ppm; potato at 0.10 ppm; potato, wet peel at 0.15 ppm; and potato, granules/flakes at 0.20 ppm

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to “object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0176 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 21, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400,

Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it “Tolerance Petition Fees.”

EPA is authorized to waive any fee requirement “when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.” For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket ID number OPP–2002–0176, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your

request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes time limited tolerances under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995

(NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under FFDCA section 408, such as the [tolerances] in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

August 12, 2002.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.498 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.498 Sulfentrazone; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* * * * *		
Flax, seed	0.20	12/31/04

Commodity	Parts per million	Expiration/revocation date
Potato	0.10	12/31/04
Potato, granules/flakes	0.20	12/31/04
Potato, wet peel	0.15	12/31/04

* * * * *

[FR Doc. 02-20989 Filed 8-20-02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-2002-0178; FRL-7192-2]

Clomazone; Pesticide Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes for tolerances for residues of clomazone in or on peppermint tops and spearmint tops. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 21, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0178, must be received on or before October 21, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0178 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this Action Apply to Me?**

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide

manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0178. The official record consists of the documents specifically referenced in this action, and other information

related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of July 17, 2002 (67 FR 46981) (FRL-7185-8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 2E6407) by IR-4, 681 U.S. Highway # 1 South, North Brunswick, New Jersey 08902-3390. This notice included a summary of the petition prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.425 be amended by establishing tolerances for residues of the herbicide clomazone, 2-(2-chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone, in or on peppermint tops and spearmint tops at 0.05 part per million (ppm).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of clomazone on peppermint tops and spearmint tops at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by clomazone is discussed in Unit III.A. of the Final Rule on Clomazone Pesticide Tolerance published in the **Federal Register** of February 14, 2001 (66 FR 10196) (FRL-6764-2).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory

animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF ($RfD = NOAEL / UF$). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = $NOAEL / exposure$) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure} / exposures$) is calculated. A summary of the toxicological endpoints for clomazone used for human risk assessment is discussed in Unit III.B. of the Final Rule on Clomazone Pesticide Tolerance published in the **Federal Register** of February 14, 2001 (66 FR 10196).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.425) for the residues of clomazone, in or on a variety

of raw agricultural commodities ranging from 0.1 to 0.05 ppm as follows: Snaps beans; cabbage; cottonseed; cucumber; succulent peas; peppers; pumpkins; rice grain; rice straw; soybeans; summer squash; winter squash; sugar cane; sweet potato; cucurbit vegetables; and tuberous and corm vegetables (except potato). Risk assessments were conducted by EPA to assess dietary exposures from clomazone in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A Tier 1 acute analysis was performed for females 13-50 years old using existing and recommended tolerance level residues, 100 percent of crop treated (% CT) information, and DEEM® default processing factors.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 1 chronic analysis was performed for the general U.S. population and all population subgroups using existing and recommended tolerance level residues, 100% CT information, and DEEM® default processing factors.

iii. *Cancer.* The Agency has classified clomazone as a "not likely human carcinogen" based on the lack of a carcinogenic response in rats and mice and the lack of mutagenic concern. Therefore, a cancer risk assessment was not performed for this action.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for clomazone in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on

the physical characteristics of clomazone.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to clomazone, they are further discussed in Unit II.E.

The EECs were based on the proposed uses of clomazone as specified on the CommandR 3 ME label (maximum application rate = 1.25 pound active ingredient per acre (lb ai/A)).

i. *Surface water.* The maximum acute and chronic surface water EECs for both parent clomazone and FMC 65317 were estimated by the Tier 1 screening models GENEEC and GENEECX. For

surface water, the maximum acute EEC was 95 parts per billion (ppb) and the maximum chronic (56-day) EEC was 68 ppb. EPA's interim policy allows the 56-day GENEEC value to be divided by an adjustment factor of 3 to obtain a value for chronic risk assessment calculations. Therefore, a surface water value of 23 ppb was used for chronic risk assessment.

ii. *Ground water.* The predicted maximum ground water EEC for both parent clomazone and FMC 65317, using the Tier 1 screening model SCI-GROW2, was 2.4 ppb which was considered as both an acute and chronic value for risk assessment purposes.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Clomazone is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether clomazone has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, clomazone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that clomazone has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the

completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of susceptibility of rat or rabbit fetuses to *in utero* exposure in the available developmental studies. In the 2-generation reproduction study, no qualitative or quantitative evidence of increased susceptibility was observed.

3. *Conclusion.* There is a complete toxicity database for clomazone and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA factor was reduced to 1X because of the following reasons: There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required; and the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children (there are currently no registered residential uses).

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be

taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable

data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary

exposure from food to clomazone will occupy <1% of the aPAD for females 13 years and older at the 95th percentile. Thus, the acute dietary risk associated with the existing and proposed uses of clomazone does not exceed EPA's level of concern (>100% aPAD). However, there is potential for acute dietary exposure to clomazone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLOMAZONE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50 years old	1.0	<1.0	95	2.4	30,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clomazone from food will utilize <1% of the cPAD for the U.S. population, and all population

subgroups. There are no residential uses for clomazone that result in chronic residential exposure to clomazone. However, there is potential for chronic dietary exposure to clomazone in drinking water. After calculating

DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO CLOMAZONE

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.84	<1	23	2.4	29,000
All infants (<1 year old)	0.84	<1	23	2.4	8,400
Children (1–6 years old)	0.84	<1	23	2.4	8,400
Females(13–50 years old)	0.84	<1	23	2.4	25,000

3. *Short and intermediate-term risk.* Short and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Clomazone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* The Agency has classified clomazone as a "not likely human carcinogen" based on the lack of a carcinogenic response in rats and mice and the lack of mutagenic concern. Therefore, no cancer risk is expected.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to clomazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for the determination of the residues of clomazone in plants. Briefly, samples are acid hydrolyzed, hexane extracted, Na₂CO₃ washed, and cleaned-up with a Florisil® column. The resulting samples are analyzed by gas chromatography (GC) using a nitrogen phosphorus detector (NPD) or mass spectrometer (MS). The limit of quantitation (LOQ) for this method is 0.05 ppm. A confirmatory procedure (GC/MS-SIM) is available (Method I, PAM II).

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone

number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican maximum residue limits (MRLs) for residues of clomazone in/on mint.

V. Conclusion

Therefore, tolerances are established for residues of clomazone, 2-(2-chlorophenyl)methyl- 4,4-dimethyl-3-isoxazolidinone, in or on peppermint tops and spearmint tops at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those

regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0178 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 21, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that

fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP-2002-0178, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the

requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General

of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 16, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.425 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.425 Clomazone; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Peppermint, tops	* * 0.05
* * *	* *
Spearmint, tops	* * 0.05
* * *	* *

* * * * *

[FR Doc. 02-21278 Filed 8-16-02; 4:19 pm]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRL-7264-1]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) today is granting a petition submitted by the United States Department of Energy Savannah River Operations Office

(DOE-SR) to exclude (or “delist”) certain hazardous wastes from the lists of hazardous wastes under the Resource Conservation and Recovery Act (RCRA). DOE-SR generated the petitioned waste by treating wastes from various activities at the Savannah River Site (SRS). The petitioned waste meets the definitions of listed RCRA hazardous wastes F006 and F028. DOE-SR petitioned EPA to grant a one-time, generator-specific delisting for its F006 and F028 waste, because DOE-SR believes that its waste does not meet the criteria for which these types of wastes were listed. The waste is a radioactive mixed waste (RMW) because it is both a RCRA hazardous waste and a radioactive waste. EPA reviewed all of the waste-specific information provided by DOE-SR, performed calculations, and determined that the waste, which has a low level of radioactivity, could be disposed in a landfill for low-level radioactive waste without harming human health and the environment. The petition is for a one-time delisting, because the petitioned waste has been generated, will be completely disposed of at one time, and will not be generated again. Today’s final rule grants DOE-SR’s petition to delist its F006 and F028 waste. No public comments on the proposed rule were received. Today’s final action means that DOE-SR’s petitioned waste will no longer be classified as F006 and F028, and will not be subject to regulation as a hazardous waste under Subtitle C of RCRA, provided that it is disposed in a low-level radioactive waste landfill, in accordance with the Atomic Energy Act. The waste will still be subject to the Atomic Energy Act and local, State, and Federal regulations for low-level radioactive solid wastes that are not RCRA hazardous wastes.

EFFECTIVE DATE: This rule is effective on August 21, 2002.

ADDRESSES: The RCRA regulatory docket for this final rule is located at the EPA Library, U.S. Environmental Protection Agency, Region 4, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303, and is available for viewing from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays.

The reference number for this docket is R4-01-02-DOESRSF. The public may copy material from any regulatory docket at no cost for the first 100 pages, and at a cost of \$0.15 per page for additional copies. For copying at the South Carolina Department of Health and Environmental Control (SCDHEC), please see below.

FOR FURTHER INFORMATION CONTACT: For general and technical information concerning this final rule, please contact Judy Sophianopoulos, RCRA Enforcement and Compliance Branch (Mail Code 4WD-RCRA), U.S. Environmental Protection Agency, Region 4, Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562-8604, or call, toll free (800) 241-1754, and leave a message, with your name and phone number, for Ms. Sophianopoulos to return your call. Questions may also be e-mailed to Ms. Sophianopoulos at sophianopoulos.judy@epa.gov. You may also contact Myra C. Reece, Director, South Carolina Department of Health and Environmental Control, Lower Savannah District Environmental Quality Control, 218 Beaufort Street, NE., Aiken, South Carolina 29801, Phone: (803) 641-7670. If you wish to copy documents at SCDHEC, Lower Savannah District Environmental Quality Control, please contact Ms. Reece for copying procedures and costs.

SUPPLEMENTARY INFORMATION: The contents of today's preamble are listed in the following outline:

- I. Background
 - A. What Is a Delisting Petition?
 - B. What Laws and Regulations Give EPA the Authority to Delist Wastes?
 - C. What is the History of this Rulemaking?
- II. Summary of Delisting Petition Submitted by the United States Department of Energy Savannah River Operations Office (DOE-SR)
 - A. What Waste Did DOE-SR Petition EPA to Delist?
 - B. What Information Did DOE-SR Submit to Support This Petition?
- III. EPA's Evaluation and Final Rule
 - A. What Decision Is EPA Finalizing and Why?
 - B. What Are the Terms of This Exclusion?
 - C. When Is the Delisting Effective?
 - D. How Does This Action Affect the States?
- IV. Public Comments Received on the Proposed Exclusion
 - A. Who Submitted Comments on the Proposed Rule?
 - B. Comments and Responses From EPA
- V. Analytical and Regulatory Requirements
 - A. Executive Order 12866: Regulatory Planning and Review
 - B. What Economic and Equity Analyses Were Completed in Support of the Proposed Delisting for DOE-SR's Petitioned Waste: Residue from Treating M-Area Waste by Vitrification and Cementitious Treatability Samples?
 - C. What Substantive Comments Were Received on the Cost/Economic Aspects of the Proposed Delisting for DOE-SR's Petitioned Waste: Residue from Treating M-Area Waste by Vitrification and Cementitious Treatability Samples?
 - D. What Are the Potential Costs and Benefits of Today's Final Rule?

- E. What Consideration Was Given to Small Entities Under the Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*?
- F. Was the Unfunded Mandates Reform Act Considered in this Final Rule?
- G. Were Equity Issues and Children's Health Considered in this Final Rule?
 1. Executive Order 12898: Environmental Justice
 2. Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks"
- H. What Consideration Was Given to Tribal Governments?
- I. Were Federalism Implications Considered in Today's Final Rule?
- J. Were Energy Impacts Considered?
- VI. Paperwork Reduction Act
- VII. National Technology Transfer and Advancement Act of 1995
- VIII. The Congressional Review Act (5 U.S.C. 801 *et seq.*, as Added by the Small Business Regulatory Enforcement Fairness Act of 1996)

I. Background

A. What Is a Delisting Petition?

A delisting petition is a request made by a hazardous waste generator to exclude one or more of his/her wastes from the lists of RCRA-regulated hazardous wastes in §§ 261.31, 261.32, and 261.33 of Title 40 of the Code of Federal Regulations (40 CFR 261.31, 261.32, and 261.33). The regulatory requirements for a delisting petition are in 40 CFR 260.20 and 260.22. EPA, Region 6 has prepared a guidance manual, *Region 6 Guidance Manual for the Petitioner*,¹ which is recommended by EPA Headquarters in Washington, DC and all EPA Regions.

B. What Laws and Regulations Give EPA the Authority To Delist Wastes?

On January 16, 1981, as part of its final and interim final regulations implementing section 3001 of RCRA, EPA published an amended list of hazardous wastes from non-specific and specific sources. This list has been amended several times, and is published in 40 CFR 261.31 and 261.32. These wastes are listed as hazardous because they exhibit one or more of the characteristics of hazardous wastes identified in subpart C of part 261 (*i.e.*, ignitability, corrosivity, reactivity, and toxicity) or meet the criteria for listing contained in § 261.11 (a)(2) or (a)(3). Discarded commercial chemical product wastes which meet the listing criteria are listed in § 261.33(e) and (f).

¹ This manual may be down-loaded from Region 6's Web site at the following URL address: http://www.epa.gov/earth1r6/6pd/rcra_c/pd-o/dlistpdf.htm.

Individual waste streams may vary, however, depending on raw materials, industrial processes, and other factors. Thus, while a waste that is described in these regulations generally is hazardous, a specific waste from an individual facility meeting the listing description may not be. For this reason, §§ 260.20 and 260.22 provide an exclusion procedure, allowing persons to demonstrate that a specific waste from a particular generating facility should not be regulated as a hazardous waste.

To have their wastes excluded, petitioners must show, first, that wastes generated at their facilities do not meet any of the criteria for which the wastes were listed. See § 260.22(a) and the background documents for the listed wastes. Second, the Administrator must determine, where he/she has a reasonable basis to believe that factors (including additional constituents) other than those for which the waste was listed could cause the waste to be a hazardous waste, that such factors do not warrant retaining the waste as a hazardous waste. Accordingly, a petitioner also must demonstrate that the waste does not exhibit any of the hazardous waste characteristics (*i.e.*, ignitability, reactivity, corrosivity, and toxicity), and must present sufficient information for the EPA to determine whether the waste contains any other toxicants at hazardous levels. See § 260.22(a), 42 U.S.C. 6921(f), and the background documents for the listed wastes. Although wastes which are "delisted" (*i.e.*, excluded) have been evaluated to determine whether or not they exhibit any of the characteristics of hazardous waste, generators remain obligated under RCRA to determine whether or not their wastes continue to be nonhazardous based on the hazardous waste characteristics (*i.e.*, characteristics which may be promulgated subsequent to a delisting decision.)

In addition, residues from the treatment, storage, or disposal of listed hazardous wastes and mixtures containing listed hazardous wastes are also considered hazardous wastes. See 40 CFR 261.3 (a)(2)(iv) and (c)(2)(i), referred to as the "mixture" and "derived-from" rules, respectively. Such wastes are also eligible for exclusion and remain hazardous wastes until excluded. On December 6, 1991, the U.S. Court of Appeals for the District of Columbia vacated the "mixture/derived-from" rules and remanded them to the EPA on procedural grounds. *Shell Oil Co. v. EPA*, 950 F.2d 741 (D.C. Cir. 1991). On March 3, 1992, EPA reinstated the mixture and derived-from rules, and solicited comments on other

ways to regulate waste mixtures and residues (57 FR 7628). These rules became final on October 30, 1992 (57 FR 49278), and should be consulted for more information regarding waste mixtures and solid wastes derived from treatment, storage, or disposal of a hazardous waste. On May 16, 2001, EPA amended the mixture and derived-from rules for certain types of wastes (66 FR 27218 and 66 FR 27266). The mixture and derived-from rules are codified in 40 CFR 261.3, paragraphs (a)(2)(iv) and (c)(2)(i). EPA plans to address all waste mixtures and residues when the final portion of the Hazardous Waste Identification Rule (HWIR) is promulgated.

On October 10, 1995, the Administrator delegated to the Regional Administrators the authority to evaluate and approve or deny petitions submitted in accordance with §§ 260.20 and 260.22 by generators within their Regions (National Delegation of Authority 8–19) in States not yet authorized to administer a delisting program in lieu of the Federal program. On March 11, 1996, the Regional Administrator of EPA, Region 4, redelegated delisting authority to the Director of the Waste Management Division (Regional Delegation of Authority 8–19).

C. What is the History of This Rulemaking?

The United States Department of Energy Savannah River Operations Office (DOE–SR), Aiken, South Carolina (DOE–SR), is seeking a delisting for vitrified radioactive mixed waste (RMW) generated at the Savannah River Site (SRS) in Aiken, South Carolina. The petitioned waste meets the listing definitions of F006 and F028 in § 261.31² and was generated by vitrification treatment of F006 and F027³ waste from the SRS—Area where nuclear reactor components were produced. The petitioned waste also includes a small volume of non-vitrified

waste which consists of cementitious treatability samples (EPA Hazardous Waste No. F006).

The hazardous constituents of concern⁴ for which F006 was listed are cadmium, hexavalent chromium, nickel, and cyanide (complexed). F028 was listed for tetra-, penta-, and hexachlorodibenzo-p-dioxins; tetra-, penta-, and hexachlorodibenzofurans; tri-, tetra-, and pentachlorophenols and their chlorophenoxy derivative acids, esters, ethers, amine and other salts. DOE–SR petitioned the EPA to exclude its F028 waste (generated from thermal treatment of F027 waste) and F006 waste because DOE–SR believes that the petitioned waste does not meet the criteria for which the waste was listed. DOE–SR claims that its F006 and F028 waste will not be hazardous because the constituents of concern for which F006 and F028 are listed are either not present or present only at such low concentrations that the waste does not meet the criteria in § 261.11(a)(3) for listing a waste as hazardous. DOE–SR also believes that this waste will not be hazardous for any other reason (*i.e.*, there will be no additional constituents or factors that could cause the waste to be hazardous⁵). Review of this petition included consideration of the original listing criteria, as well as the additional factors required by the Hazardous and Solid Waste Amendments (HSWA) of 1984. See section 222 of HSWA, 42 U.S.C. 6921(f), and 40 CFR 260.22(d)(2)–(4).

DOE–SR petitioned EPA, Region 4, in September 1996 and submitted revised petitions in September 1998 and September 2000, to exclude this F006 and F028 waste, on a one-time, generator-specific basis, from the lists of hazardous wastes in 40 CFR part 261, subpart D.

As a result of the EPA's evaluation of DOE–SR's petition, the Agency proposed to grant a delisting to DOE–SR on March 15, 2002. See 67 FR 11639–11651, March 15, 2002 for details. EPA received no public comments on the proposed rule and today's rulemaking finalizes the proposed decision to grant DOE–SR's petition for delisting.

II. Summary of Delisting Petition Submitted by the United States Department of Energy Savannah River Operations Office (DOE–SR)

A. What Waste Did DOE–SR Petition EPA To Delist?

DOE–SR petitioned EPA, Region 4, in September 1996 and submitted revised petitions in September 1998 and September 2000, to exclude 538 cubic yards of vitrified F006 and F028 waste and 0.12 cubic yards of cementitious treatability sample F006 waste, on a one-time, generator-specific basis, from the lists of hazardous wastes in 40 CFR part 261, subpart D. DOE–SR treated ten waste streams generated in the Savannah River Site M-Area from 1983 through 1999, by vitrification. The treatment residue of all these streams is the 538 cubic yards of petitioned waste. The 0.12 cubic yards of petitioned waste comes from treatability studies of cementing F006 waste, and is referred to as cementitious treatability samples.

B. What Information Did DOE–SR Submit To Support This Petition?

In support of its petition, DOE–SR submitted: (1) Descriptions⁶ of the waste streams that contributed to the petitioned waste, the areas where the contributing waste streams were generated, and the vitrification treatment process that generated the petitioned waste; (2) Material Safety Data Sheets (MSDSs) for all chemicals used in processes that generated the waste streams from which the petitioned waste was derived and the vitrification process that generated the petitioned waste; (3) the total volume of petitioned waste generated; (4) results of analysis of untreated waste and the petitioned waste for all constituents in appendix VIII of 40 CFR part 261 or appendix IX of part 264; (5) results of the analysis of leachate obtained by means of the Toxicity Characteristic Leaching Procedure (TCLP), SW–846 Method 1311), from the petitioned waste and historical results obtained by the Extraction Procedure Toxicity leaching method ((EPTox), SW–846 Method 1310); (6) results of the determinations for the hazardous characteristics of ignitability, corrosivity, and reactivity, in these wastes; and (7) results of the analysis of the petitioned waste by means of the Multiple Extraction Procedure (MEP), SW–846 Method 1320⁷.

² F006: "Wastewater treatment sludges from electroplating operations except from the following processes: (1) Sulfuric acid anodizing of aluminum; (2) tin plating on carbon steel; (3) zinc plating (segregated basis) on carbon steel; (4) aluminum or zinc-aluminum plating on carbon steel; and (6) chemical etching and milling of aluminum."

F028: "Residues resulting from the incineration or thermal treatment of soil contaminated with EPA Hazardous Waste Nos. F020, F021, F023, F026, and F027."

³ F027: "Discarded unused formulations containing tri-, tetra-, or pentachlorophenol or discarded unused formulations containing compounds derived from these chlorophenols. (This listing does not include formulations containing Hexachlorophene synthesized from prepurified 2,4,5-tri-chlorophenol as the sole component.)"

⁴ The hazardous constituents of concern for every listed waste are in *Appendix VII of Part 261—Basis for Listing Hazardous Waste*.

⁵ Note that the waste remains subject to the Atomic Energy Act because of its radioactivity.

⁶ Detailed descriptions may be found in the DOE–SR's Approved Site Treatment Plan (1996), developed pursuant to the Federal Facility Compliance Act of 1992.

⁷ "SW–846" means EPA's Publication SW–846, "Test Methods for Evaluating Solid Waste,

Please see the proposed rule, 67 FR 11639–11651, March 15, 2002 for details on DOE–SR's analytical data, vitrification process, and generation process for the petitioned waste. A summary of analytical data was presented in Preamble Section II, Table 1B of the proposed rule (67 FR 11639–11651, March 15, 2002). EPA does not generally verify submitted test data before proposing delisting decisions. The sworn affidavit submitted with this petition binds the petitioner to present truthful and accurate results. The Agency, however, has maintained a

spot-check sampling and analysis program to verify the representative nature of data for some percentage of the submitted petitions. A spot-check visit to a selected facility may be initiated before or after granting a delisting. Section 3007 of RCRA gives EPA the authority to conduct inspections to determine if a delisted waste is meeting the delisting conditions.

III. EPA's Evaluation and Final Rule

A. What Decision Is EPA Finalizing and Why?

In today's final rule, EPA is finalizing the delisting exactly as proposed in 67 FR 11639–11651, March 15, 2002. Appendix IX, Table 1 of 40 CFR part 261 is amended as proposed (67 FR 11650–11651). Table 1 below, which is a reproduction of Table 2 of the proposed rule (67 FR 11645–11646), summarizes delisting and risk levels calculated by DRAS for DOE–SR's petitioned waste.

TABLE 1: DELISTING AND RISK LEVELS CALCULATED BY DRAS WITH EPACMTP MODEL FOR DOE–SR'S PETITIONED WASTE

Constituent	Delisting level (mg/l TCLP)	DAF	DRAS-calculated risk for maximum concentration of carcinogen in waste	DRAS-calculated hazard quotient for maximum concentration of non-carcinogen in waste
Arsenic	0.0649	1,330	3.47×10^{-7}	
Barium	* 5,070; 3,860 Based on MCL	1,930		5.66×10^{-6}
Beryllium (Carcinogenic Effect)	Not Enough Information: Effect Based on Inhalation 28.8 Based on MCL.	7.21×10^3	2.13×10^{-11}	
Beryllium (Non-Carcinogenic Effect)	541; 28.8 Based on MCL	7.21×10^3		2.16×10^{-6}
Cadmium (Carcinogenic Effect)	Not Enough Information: Effect Based on Inhalation; 10.4 Based on MCL.	2,080	4.17×10^{-15}	
Cadmium (Non-Carcinogenic Effect)	* 39; 10.4 Based on MCL	2,080		1.15×10^{-4}
Chromium (Hexavalent; Carcinogenic Effect)	Not Enough Information: Effect Based on Inhalation; 107 Based on MCL.	1,070	5.30×10^{-12}	
Chromium (Not Hexavalent; Non-Carcinogenic Effect).	* 1.50×10^7 ; 2.67×10^4 Based on MCL	2.67×10^5		5.48×10^{-7}
Lead	* 5,200	3.46×10^5		(**)
Nickel	1,960	2,610		5.64×10^{-4}
Silver	* 266	1420		3.71×10^{-5}
Fluoride	Not Enough Information; 4,990 Based on MCL	1,250		(***)
Acetonitrile	847	1,320		6.00×10^{-7}
Total Hazard Quotient for All Waste Constituents.			1.09×10^{-3}
Total Carcinogenic Risk for the Waste (due to Arsenic, Beryllium, Cadmium, and Hexavalent Chromium).		3.48×10^{-7}	

* These levels are all greater than the Toxicity Characteristic (TC) regulatory level in 40 CFR 261.24. A waste cannot be delisted if it exhibits a hazardous characteristic; therefore, the delisting level for each of these constituents could not be greater than the TC level of 100 for Barium; 1.0 for Cadmium; 5.0 for Chromium; 5.0 for Lead; and 5.0 for Silver. MCL = Maximum Contaminant Level of National Primary Drinking Water Standards.

** Not Enough Information: There is No Reference Dose for Lead.

*** Not Enough Information.

After reviewing the analytical data and information on processes and vitrification feed materials that DOE–SR submitted in the delisting petition, EPA developed a list of constituents of concern and calculated delisting levels and risks using Region 6 Delisting Risk Assessment Software (DRAS) and Dilution Attenuation Factors (DAFs) from the EPA Composite Model for Landfills with Transformation Products (EPACMTP) (67 FR 11639–11651,

March 15, 2002). EPA requested public comment on this proposed method of calculating delisting levels and risks for DOE–SR's petitioned waste. No public comments were received.

EPA also requested comment on three additional methods of evaluating DOE–SR's delisting petition and determining delisting levels: (1) Use of the Multiple Extraction Procedure (MEP), SW–846 Method 1320, to evaluate the long-term resistance of the waste to leaching in a

landfill; (2) comparing total concentrations of constituents in the waste to the results obtained by DRAS for total concentrations; and (3) comparing concentrations of constituents in the waste and waste leachate to the Land Disposal Restrictions (LDR) Universal Treatment Standards. (1) The MEP results for DOE–SR's petitioned waste indicated long-term resistance to leaching in a landfill. For example, less than 1% of

the available nickel would be expected to leach from the waste in more than 100 years (67 FR 11646). (2) Total concentrations of constituents in the petitioned waste were several orders of magnitude below results obtained by DRAS for total concentrations. The maximum reported total concentrations for DOE-SR's petitioned waste were all below the following levels (mg/kg): Arsenic—10; Barium—200; Beryllium—10; Cadmium—10; Chromium—500; Lead—200; Nickel—10,000; Silver—20; Acetonitrile—1.0, and Fluoride—1.0. (3) The petitioned waste meets the LDR Universal Treatment Standards, as required by the Federal Facility Compliance Agreement. No public comments were received.

B. What Are the Terms of This Exclusion?

In today's final rule, EPA is excluding DOE-SR's petitioned waste from being listed as F006 and F028, based on descriptions of waste management and waste history, evaluation of the results of waste sample analysis, and on the requirement that DOE-SR's petitioned waste must be disposed in accordance with the Atomic Energy Act. This exclusion is valid only if the petitioner disposes of the waste in a low-level radioactive waste landfill in accordance with the Atomic Energy Act, as required by the amended Table 1 of appendix IX of 40 CFR part 261. Under these conditions, the petitioned waste is not subject to regulation under 40 CFR parts 262 through 268 and the permitting standards of 40 CFR part 270. Although management of the waste covered by this petition is relieved from Subtitle C jurisdiction, the waste remains a solid waste under RCRA and a low-level radioactive waste under the Atomic Energy Act. As such, the waste must be handled in accordance with all applicable Federal, State, and local solid waste management and low-level radioactive waste regulations. Pursuant to RCRA section 3007, EPA may also sample and analyze the waste to verify reported analytical data.

C. When Is the Delisting Effective?

This final rule is effective on August 21, 2002. The Hazardous and Solid Waste Amendments of 1984 amended section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here, because this final rule reduces the existing requirements for the petitioner. In light of the unnecessary hardship and expense that would be imposed on this petitioner by an effective date six

months after publication and the fact that a six-month deadline is not necessary to achieve the purpose of section 3010, EPA believes that this exclusion should be effective immediately upon final publication. These reasons also provide a basis for making this rule effective immediately, upon final publication, under the Administrative Procedure Act, pursuant to 5 U.S.C. 553(d).

D. How Does This Action Affect the States?

This final rule is issued under the Federal (RCRA) delisting program. States, however, are allowed to impose their own, non-RCRA regulatory requirements that are more stringent than EPA's, pursuant to section 3009 of RCRA. These more stringent requirements may include a provision which prohibits a Federally issued exclusion from taking effect in the States. Because a petitioner's waste may be regulated under a dual system (*i.e.*, both Federal and State programs), petitioners are urged to contact State regulatory authorities to determine the current status of their wastes under the State laws. Furthermore, some States are authorized to administer a delisting program in lieu of the Federal program, *i.e.*, to make their own delisting decisions. Therefore this final exclusion does not apply in those authorized States. If the petitioned waste will be transported to any State with delisting authorization, SRS must obtain delisting authorization from that State before the waste may be managed as nonhazardous in that State.

Under section 3006 of RCRA, EPA may authorize qualified States to administer the RCRA hazardous waste program within the State. *See* 40 CFR part 271 for the overall standards and requirements for authorization. Following authorization, the State requirements authorized by EPA apply in lieu of equivalent Federal requirements and become Federally enforceable as requirements of RCRA. EPA maintains independent authority to bring enforcement actions under RCRA sections 3007, 3008, 3013, and 7003. Authorized States also have independent authority to bring enforcement actions under State law. A State may receive authorization by following the approval process described under 40 CFR part 271.

After a State receives initial authorization, new Federal requirements promulgated under RCRA authority existing prior to the 1984 Hazardous and Solid Waste Amendments (HSWA) do not apply in that State until the State adopts and

receives authorization for equivalent State requirements. The State must adopt such requirements to maintain authorization.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), new Federal requirements and prohibitions imposed pursuant to HSWA provisions take effect in authorized States at the same time that they take effect in unauthorized States. Although authorized States are still required to update their hazardous waste programs to remain equivalent to the Federal program, EPA carries out HSWA requirements and prohibitions in authorized States, including the issuance of new permits implementing those requirements, until EPA authorizes the State to do so. Authorized States are required to modify their programs only when EPA promulgates Federal requirements that are more stringent or broader in scope than existing Federal requirements. RCRA section 3009 allows the States to impose standards more stringent than those in the Federal program. *See* also 40 CFR 271.1(i). Therefore, authorized States are not required to adopt Federal regulations, both HSWA and non-HSWA, that are considered less stringent.

Today's final rule is promulgated pursuant to HSWA authority, and contains provisions that are less stringent than the current Federal program. The final exclusion for DOE-SR's petitioned waste would be less stringent. Consequently, States would not be required to adopt this final exclusion as a condition of authorization of their hazardous waste programs.

IV. Public Comments Received on the Proposed Exclusion

A. Who Submitted Comments on the Proposed Rule?

No one submitted comments on the proposed rule to EPA.

B. Comments and Responses From EPA

EPA did not receive any comments.

V. Analytical and Regulatory Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, EPA must determine whether a regulatory action is significant and, therefore, subject to comprehensive review by the Office of Management and Budget (OMB), and the other provisions of the Executive Order. A significant regulatory action is defined by the Order as one that may:

- Have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or rights and obligations or recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

EPA has determined that today's final rule is not a significant regulatory action as defined by Executive Order 12866 and is, therefore, not subject to OMB comprehensive review and the other provisions of the Executive Order.

B. What Economic and Equity Analyses Were Completed in Support of the Proposed Delisting for DOE-SR's Petitioned Waste: Residue From Treating M-Area Waste by Vitrification and Cementitious Treatability Samples?

No economic and equity analyses were required in support of the March 15, 2002 proposed rule. The proposed rule applies only to a one-time generated waste at a single facility. Therefore the proposal would have had no generalized effect on industrial compliance costs and would have reduced compliance costs for the single facility, DOE-SR Savannah River Site.

C. What Substantive Comments Were Received on the Cost/Economic Aspects of the Proposed Delisting for DOE-SR's Petitioned Waste: Residue From Treating M-Area Waste by Vitrification and Cementitious Treatability Samples?

EPA received no public comments on the proposed rule to delist DO-ESR's petitioned waste.

D. What Are the Potential Costs and Benefits of Today's Final Rule?

The value of any regulatory action is traditionally measured by the net change in social welfare that it generates. All other factors being equal, a rule that generates positive net welfare would be advantageous to society, while a rule that results in negative net welfare to society should be avoided.

Today's final rule applies to a one-time generated waste at a single facility. Therefore, EPA has determined that the rule is not expected to have any generalized economic, health, or environmental effects on society.

E. What Consideration Was Given to Small Entities Under the Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et. seq.?

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's final rule on small entities, a small entity is defined either by the number of employees or by the annual dollar amount of sales/revenues. The level at which an entity is considered small is determined for each North American Industrial Classification System (NAICS) code by the Small Business Administration (SBA).

EPA has examined the potential effects today's final rule may have on small entities, as required by the RFA/Small Business Regulatory Enforcement Fairness Act (SBREFA). Today's final rule affects a one-time generated waste at a single facility, DOE-SR Savannah River Site. Therefore, EPA has determined and certifies that this rule will not have a significant economic impact on a substantial number of small entities.

F. Was the Unfunded Mandates Reform Act Considered in This Final Rule?

Executive Order 12875, "Enhancing the Intergovernmental Partnership" (October 26, 1993), called on federal agencies to provide a statement supporting the need to issue any regulation containing an unfunded federal mandate and describing prior consultation with representatives of affected state, local, and tribal governments.

Signed into law on March 22, 1995, the Unfunded Mandates Reform Act (UMRA) supersedes Executive Order 12875, reiterating the previously established directives while also imposing additional requirements for federal agencies issuing any regulation containing an unfunded mandate.

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private

sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any single year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, the Agency must develop a small government agency plan, as required under section 203 of UMRA. This plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule is not subject to the requirements of sections 202 and 205 of UMRA. Today's final rule will not result in \$100 million or more in incremental expenditures. The aggregate annualized incremental social costs for today's final rule are projected to be near zero. Furthermore, today's final rule is not subject to the requirements of section 203 of UMRA. Section 203 requires agencies to develop a small government Agency plan before establishing any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments. EPA has determined that this final rule will not significantly or uniquely affect small governments.

G. Were Equity Issues and Children's Health Considered in This Final Rule?

By applicable executive order, we are required to consider the impacts of today's rule with regard to environmental justice and children's health.

1. Executive Order 12898: Environmental Justice

Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Population" (February 11, 1994), is designed to address the environmental and human health conditions of minority and low-income populations. EPA is committed to addressing environmental justice concerns and has assumed a leadership role in environmental justice initiatives to enhance environmental quality for all citizens of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, income, or net worth bears disproportionately high and adverse human health and environmental impacts as a result of EPA's policies, programs, and activities. In response to Executive Order 12898, and to concerns voiced by many groups outside the Agency, EPA's Office of Solid Waste and Emergency Response (OSWER) formed an Environmental Justice Task Force to analyze the array of environmental justice issues specific to waste programs and to develop an overall strategy to identify and address these issues (OSWER Directive No. 9200.3-17). Today's final rule applies to a one-time generated waste at a single facility. We have no data indicating that today's final rule would result in disproportionately negative impacts on minority or low income communities.

2. Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks"

"Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. Today's final rule is not subject to the Executive Order because it is not economically significant, as defined in Executive Order 12866."

H. What Consideration Was Given to Tribal Governments?

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

Today's final rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. Today's final rule will not significantly or uniquely affect the communities of Indian tribal governments, nor impose substantial direct compliance costs on them.

I. Were Federalism Implications Considered in Today's Final Determination?

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Today's final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. Thus, Executive Order 13132 does not apply to this final rule.

J. Were Energy Impacts Considered?

Executive Order 13211, "Actions Concerning Regulations That Affect Energy Supply, Distribution, or Use"

(May 18, 2001), addresses the need for regulatory actions to more fully consider the potential energy impacts of the proposed rule and resulting actions. Under the Order, agencies are required to prepare a Statement of Energy Effects when a regulatory action may have significant adverse effects on energy supply, distribution, or use, including impacts on price and foreign supplies. Additionally, the requirements obligate agencies to consider reasonable alternatives to regulatory actions with adverse effects and the impacts the alternatives might have upon energy supply, distribution, or use.

Today's final rule applies to a one-time generated waste at a single facility and is not likely to have any significant adverse impact on factors affecting energy supply. EPA believes that Executive Order 13211 is not relevant to this action.

VI. Paperwork Reduction Act

This final determination does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Because there are no paperwork requirements as part of this final rule, EPA is not required to prepare an Information Collection Request (ICR) in support of today's action.

VII. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rule involves evaluation of environmental monitoring or measurement. Consistent with the Agency's Performance Based Measurement System ("PBMS"), EPA proposed not to require the use of specific, prescribed analytical methods, except when required by regulation in 40 CFR parts 260 through 270. Therefore, today's final rule allows the use of any method that meets the prescribed performance criteria. The

PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified. Measurements were completed by the facility prior to publication of the proposed rule and EPA evaluated the data before publishing the proposed rule and promulgating today's final rule.

VIII. The Congressional Review Act (5 U.S.C. 801 *et seq.*, as Added by the Small Business Regulatory Enforcement Fairness Act of 1996)

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a

copy of the rule, to each House of the Congress and to the Comptroller General of the United States.

The EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability. Section 804 exempts from section 801 the following types of rules: rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedures, or practice that do not substantially affect the rights or obligations of non-agency parties. *See* 5 U.S.C. 804(3). A "major rule" cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will become effective on the date of publication as a final rule in the **Federal Register**.

List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Authority: Sec. 3001(f) RCRA, 42 U.S.C. 6921(f).

Dated: August 8, 2002.

Jewell A. Harper,

Acting Director, Waste Management Division.

For the reasons set out in the preamble, 40 CFR part 261 is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

2. In Table 1 of appendix IX, part 261 add the following wastestream in alphabetical order by facility to read as follows:

Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22.

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
* Savannah River Site (SRS)	* Aiken, South Carolina	* Vitrified waste (EPA Hazardous Waste Nos. F006 and F028) that the United States Department of Energy Savannah River Operations Office (DOE-SR) generated by treating the following waste streams from the M-Area of the Savannah River Site (SRS) in Aiken, South Carolina, as designated in the SRS Site Treatment Plan: W-004, Plating Line Sludge from Supernate Treatment; W-995, Mark 15 Filter Cake; W-029, Sludge Treatability Samples (glass and cementitious); W-031, Uranium/Chromium Solution; W-037, High Nickel Plating Line Sludge; W-038, Plating Line Sump Material; W-039, Nickel Plating Line Solution; W-048, Soils from Spill Remediation and Sampling Programs; W-054, Uranium/Lead Solution; W-082, Soils from Chemicals, Metals, and Pesticides Pits Excavation; and Dilute Effluent Treatment Facility (DETF) Filtercake (no Site Treatment Plan code). This is a one-time exclusion for 538 cubic yards of waste (hereinafter referred to as "DOE-SR Vitrified Waste") that was generated from 1996 through 1999 and 0.12 cubic yard of cementitious treatability samples (hereinafter referred to as "CTS") generated from 1988 through 1991 (EPA Hazardous Waste No. F006). The one-time exclusion for these wastes is contingent on their being disposed in a low-level radioactive waste landfill, in accordance with the Atomic Energy Act, after [insert date of final rule.] DOE-SR has demonstrated that concentrations of toxic constituents in the DOE-SR Vitrified Waste and CTS do not exceed the following levels: (1) <i>TCLP Concentrations:</i> All leachable concentrations for these metals did not exceed the Land Disposal Restrictions (LDR) Universal Treatment Standards (UTS): (mg/l TCLP): Arsenic—5.0; Barium—21; Beryllium—1.22; Cadmium—0.11; Chromium—0.60; Lead—0.75; Nickel—11; and Silver—0.14. In addition, none of the metals in the DOE-SR Vitrified Waste exceeded the allowable delisting levels of the EPA, Region 6 Delisting Risk Assessment Software (DRAS): (mg/l TCLP): Arsenic—0.0649; Barium—100.0; Beryllium—0.40; Cadmium—1.0; Chromium—5.0; Lead—5.0; Nickel—10.0; and Silver—5.0. These metal concentrations were measured in the waste leachate obtained by the method specified in 40 CFR 261.24. <i>Total Concentrations in Unextracted Waste:</i> The total concentrations in the DOE-SR Vitrified Waste, not the waste leachate, did not exceed the following levels (mg/kg): Arsenic—10; Barium—200; Beryllium—10; Cadmium—10; Chromium—500; Lead—200; Nickel—10,000; Silver—20; Acetonitrile—1.0, which is below the LDR UTS of 38 mg/kg; and Fluoride—1.0

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		<p>(2) <i>Data Records:</i> Records of analytical data for the petitioned waste must be maintained by DOE–SR for a minimum of three years, and must be furnished upon request by EPA or the State of South Carolina, and made available for inspection. Failure to maintain the required records for the specified time will be considered by EPA, at its discretion, sufficient basis to revoke the exclusion to the extent directed by EPA. All data must be maintained with a signed copy of the certification statement in 40 CFR 260.22(i)(12).</p> <p>(3) <i>Reopener Language:</i> (A) If, at any time after disposal of the delisted waste, DOE–SR possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or groundwater monitoring data) or any other data relevant to the delisted waste indicating that any constituent is identified at a level higher than the delisting level allowed by EPA in granting the petition, DOE–SR must report the data, in writing, to EPA within 10 days of first possessing or being made aware of that data. (B) Based on the information described in paragraph (3)(A) and any other information received from any source, EPA will make a preliminary determination as to whether the reported information requires that EPA take action to protect human health or the environment. Further action may include suspending or revoking the exclusion, or other appropriate response necessary to protect human health and the environment. (C) If EPA determines that the reported information does require Agency action, EPA will notify the facility in writing of the action believed necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing DOE–SR with an opportunity to present information as to why the proposed action is not necessary. DOE–SR shall have 10 days from the date of EPA's notice to present such information. (E) Following the receipt of information from DOE–SR, as described in paragraph (3)(D), or if no such information is received within 10 days, EPA will issue a final written determination describing the Agency actions that are necessary to protect human health or the environment, given the information received in accordance with paragraphs (3)(A) or (3)(B). Any required action described in EPA's determination shall become effective immediately, unless EPA provides otherwise.</p> <p>(4) <i>Notification Requirements:</i> DOE–SR must provide a one-time written notification to any State Regulatory Agency in a State to which or through which the delisted waste described above will be transported, at least 60 days prior to the commencement of such activities. Failure to provide such a notification will result in a violation of the delisting conditions and a possible revocation of the decision to delist.</p>

[FR Doc. 02–21287 Filed 8–20–02; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Part 102–192

Federal Management Regulation; Technical Amendments

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Correction and technical amendment to final rule.

SUMMARY: This document makes amendments to the Federal Management Regulation (FMR) in order to correct references and make a technical

amendment to the mail management regulations of the FMR.

DATES: Effective Date: August 21, 2002.

FOR FURTHER INFORMATION CONTACT:

Laurie Duarte, Regulatory Secretariat, Acquisition Policy Division (MVP), General Services Administration, 1800 F Street, NW., Washington, DC 20405, (202) 208–7312.

List of Subjects in 41 CFR Part 102–192

Government contracts, Intergovernmental relations, Reporting and recordkeeping requirements, Security measurements.

Therefore, GSA amends 41 CFR part 102–192 as set forth below:

PART 102–192—MAIL MANAGEMENT

1. The authority citation for 41 CFR part 102–192 continues to read as follows:

Authority: Sec. 2, Pub. L. 94–575, as amended, 44 U.S.C. 2904; 40 U.S.C. 486(c); Sec. 205(c), 63 Stat. 390.

§ 102–192.55 [Amended]

2. Redesignate § 192.55 as § 102–192.55.

§ 102–192.125 [Amended]

3. Amend § 102–192.125 in the introductory text by removing “§ 192.50” and adding “§ 102–192.50” in its place and in paragraph (e) by removing “(see subpart C) of this part;” and adding “(see subpart C of this part);” in its place.

Dated: August 13, 2002.

Laurie Duarte,

Regulatory Secretariat, Acquisition Policy Division.

[FR Doc. 02–21076 Filed 8–20–02; 8:45 am]

BILLING CODE 6820–24–P

Proposed Rules

Federal Register

Vol. 67, No. 162

Wednesday, August 21, 2002

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

7 CFR Part 800

RIN 0580-AA58

Review Inspection Requirements

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA

ACTION: Proposed rule.

SUMMARY: The Grain Inspection, Packers and Stockyards Administration (GIPSA) is proposing to revise the regulations under the United States Grain Standards Act (Act), as amended, to allow interested persons to specify the quality factor(s) that would be redetermined during a reinspection or appeal inspection for grade. Currently, reinspections and appeal inspections for grade must include a redetermination (i.e., a complete review or examination) of all official factors that may determine the grade, are reported on the original certificate, or are required to be shown. Requiring that all quality factors be completely reexamined during a reinspection or appeal inspection is not efficient, is time consuming, and can be costly. Further, a detailed review of the preceding inspection service is not always needed to confirm the quality of the grain. This proposed action would allow interested parties to specify which official factor(s) should be redetermined during the reinspection or appeal inspection service.

DATES: Comments must be received on or before October 21, 2002.

ADDRESSES: Written comments must be submitted to Tess Butler, GIPSA, USDA, Room 1647-S, Stop 3604, Washington, DC 20250; FAX (202) 690-2755; e-mail, comments.gipsadc@usda.gov.

All comments received will be made available for public inspection in Room 1647-South Building, 1400 Independence Avenue, SW., Washington, DC, during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: John Giler, at (202) 720-1748.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the United States Grain Standards Act (Act) (7 U.S.C. 71 *et seq.*) the Official United States Standards for Grain are used to measure and describe the physical and biological properties of grain at the time of inspection. The grade, class, and condition that are reported on the official inspection certificate are based on factors that are defined in these standards. There are three kinds of factors: condition factors, grade determining factors, and nongrade determining factors.

1. Condition factors include heating, odor (musty, sour, and commercially objectionable), infestation, special grade factors (e.g., smut and garlic), and distinctly low quality factors, such as toxic seeds. When grain is found to contain an unacceptable level of one or more of these conditions factors, it is graded U.S. Sample Grade or assigned a special grade, such as Infested.

2. Grade determining factors include, but are not limited to, test weight per bushel, foreign material, damaged kernels, and other classes. These factors are common to most grain. As the percentage of such factors increase (or decrease, as in the case of test weight per bushel), the numerical grade decreases. For example: U.S. No. 2 Hard Red Winter wheat may contain not more than 4.0% total damaged kernels, U.S. No. 3 may contain not more than 7.0%, and U.S. No. 4 may contain not more than 10.0%.

3. Non-grade determining factors include moisture in all grains, dockage in certain small grains, protein in wheat and soybeans, oil in soybeans and sunflower seed, and aflatoxin in corn. The value of each of these factors varies with crop year and end-use. Therefore, except for dockage and moisture, which must always be determined, these factors are only determined upon request.

After the sample has been analyzed for all factors, a grade is assigned to the sample equal to the lowest grade determined for any one of the factors. For example, if all of the factors were determined to be at the U.S. No. 1 level, except for one factor that was at the U.S. No. 3 level, then the lot would be graded U.S. No. 3. Therefore, the final

grade assigned to a sample or lot is directly dependent on achieving accuracy (closeness to the true value) and precision (repeatability) in the values obtained for the various grading factors. Accuracy and precision are affected mainly by the type of sampling device, the sampling procedure, and the grading factors; i.e., machine-determined values (objective), human judgement values (subjective), and sample homogeneity (inherent). The sources of variation are highly interrelated; each is involved, to some extent, in the final value ascribed to each grading factor of a lot and to the grade designation of that lot.

Due to inherent sampling and inspection variability, users of the official inspection system have an opportunity to obtain another inspection service when certificated results are questionable. That is, if an interested party disagrees with the grade or factor results assigned to a lot of grain, they may request that the official agency (or in some cases, GIPSA) reinspect the grain or ask GIPSA to perform an appeal inspection. There is a limit, however, on the number of times this can be done. From the original inspection service an interested person may obtain a reinspection service, an appeal inspection service, and a Board Appeal inspection service. The same inspection office that provided the original inspection service provides the reinspection service. The appeal inspection service is handled at one of the GIPSA field offices. The Board of Appeals and Review provides the Board Appeal inspection service, the highest level of inspection service available, in Kansas City, Missouri. The scope of the reinspection or appeal inspection is limited to the scope of the original inspection. Official criteria are considered separately from official grade and official factors when determining kind and scope. If the request specifies a different kind and scope, the request must be dismissed.

Finally, a reinspection certificate supersedes the original inspection certificate and an appeal inspection certificate supersedes the original and reinspection certificate, if a reinspection was performed. The superseded certificate(s) are considered null and void as of the date of the reinspection or appeal inspection certificate, and must be promptly surrendered. If the

superseded original certificate(s) is in the custody of the office that performed the review inspection, it is marked VOID. If the superseded certificate is not in the custody of the reviewing office at the time the reinspection or appeal inspection certificate is issued, the following statement is shown on the appeal certificate: "The superseded certificate has not been surrendered." Furthermore, each reinspection and appeal inspection certificate must clearly show the word "Reinspection" or "Appeal Inspection," and the following statement: "This certificate supersedes Certificate No. __, dated _____."

For export vessels, a reinspection or appeal inspection may be requested on either the entire lot or on a material portion (*i.e.*, part of a lot that has been found to be inferior to the contract or declared grade). When a material portion occurs, the applicant for service is entitled to one field review (either a reinspection or appeal inspection) and a Board Appeal inspection in an attempt to remove the material portion designation. If the review inspection does not eliminate the material portion designation and the applicant elects to leave the grain on board the carrier, it is considered as a separate lot and is certificated as such. If the review inspection eliminates the material portion designation, the review inspection results replace the original results on the shiplot inspection log. In such cases, no statement regarding the reinspection is required to be shown on the inspection certificate.

In addition to these restrictions, §§ 800.125 and .135 of the regulations currently require that reinspections and appeal inspections for grade must include a complete review of all official factors that: (1) May determine the grade; or (2) are reported on the original certificate; and (3) are required to be shown. Consequently, even if the official inspector who is performing the reinspection or appeal inspection finds there is only one grade-determining factor, all of the factors that were reported on the original certificate must be redetermined.

In most instances, the applicant for service does not need a complete review. Usually, applicants for a reinspection or an appeal inspection service only question the result of a specific quality factor. This is evidenced by the many applications for reinspections and appeal inspections that request a review inspection of a specific factor. In addition to being unwanted, redetermining all official factors requires significant time to complete. This increases inspection

costs and may cause delays in elevator operations.

Various industry groups have indicated that requiring all factors to be completely reviewed on reinspections and appeal inspections is usually unnecessary and always costly. But, others have indicated that the regulations must not allow official personnel to overlook questionable factor results just because the applicant for the inspection does not request that certain factors be redetermined during the course of a review inspection. Both of these views have merit. All official inspections (original, reinspection, or appeal inspection) must be accurate.

To provide effective and efficient official inspection services that better meet industry needs, GIPSA proposes that applicants for service would be allowed to specify the factor(s) that are to be redetermined as part of a reinspection or an appeal inspection service. However, reinspections for grade, appeal and Board appeal inspections for grade may include a review of any pertinent factor(s), as deemed necessary by official personnel. If there is an indication that a factor (or factors) may have been misgraded or overlooked on the previous inspection, then the factor(s) in question will be redetermined.

Under the current regulations, when official grade or official factor and official criteria are reported on the same certificate, a reinspection or appeal inspection certificate is required to show a special statement. The special statement indicates that the reinspection results or appeal or Board appeal inspection results represent the official grade, official factors or official criteria and that all other results are those of the original, reinspection, or, in the case of a Board appeal, the appeal inspection service. In formulating this proposal, GIPSA considered requiring reinspection and appeal inspection certificates to show a statement that would identify which factors were determined during the review inspection(s) and which were determined on a preceding inspection. GIPSA has not included such additional certification requirements in this proposal. However, GIPSA is seeking comments specifically about this issue, particularly from those who are currently using official inspection services.

Proposed Action

GIPSA proposes to revise § 800.125 to allow requests for reinspection to be limited to one or more grade or condition factors, and to revise § 800.135 to allow requests for appeal

inspections to be limited to one or more grade or condition factors. In addition, GIPSA is proposing to revise §§ 800.125 and 800.135 to simplify the wording of both regulations.

Executive Order 12866 and Effect on Small Entities

This proposed rule has been determined to be significant for purpose of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget (OMB). In addition, pursuant to requirements set forth in the Regulatory Flexibility Act (RFA)(5 U.S.C. 601 *et seq.*), GIPSA has considered the economic impact of this proposed rule on small entities and has determined that its provisions would not have a significant economic impact on a substantial number of small entities.

The proposed rule will affect entities engaged in shipping grain to and from points within the United States and exporting grain from the United States. GIPSA estimates there are approximately 9,500 off-farm storage facilities and 57 export elevators in the United States that could receive official inspection services by GIPSA, delegated States, or designated agencies. Official inspection services are provided by 12 GIPSA field offices, 2 Federal/State offices, 7 GIPSA suboffices, 8 delegated States, and 59 designated agencies. Under provisions of the Act, it is not mandatory for non-export grain to be officially inspected. Further, most users of the official inspection services and those entities that perform these services do not meet the requirements for small entities. Even though some users could be considered small entities, this proposed rule relieves regulatory requirements and improves the efficiency of official inspection services. No additional cost is expected to result from this action.

Requiring all reinspections and appeal inspections for grade to include a complete review of all official factors is not needed by applicants or other parties to transactions, or by official inspection personnel. Furthermore, this requirement often reduces the efficiency of providing official inspection services and may cause unnecessary delays in elevator operations. Allowing applicants to specify which official factor(s) are to be redetermined during the reinspection or appeal inspection service will improve the efficiency of the inspection service due to the time required to analyze all official quality factors.

Prior to developing this proposed rule change, GIPSA considered restricting the proposed action to either appeal

inspections or to reinspections. Our analysis was as follows:

1. Restrict Proposed Action To Appeal Inspections

GIPSA inspectors, who are assigned to specific GIPSA field offices, are the only ones who can perform appeal inspections. Currently, GIPSA has only fourteen field offices and less than 200

full-time GIPSA inspectors nationwide. Most domestic inspection services are provided by official agencies and not by GIPSA field offices. Therefore, applicants for service usually opt for a reinspection, rather than requesting an appeal inspection. (See Table 1.) The only applicants for service that would benefit from this alternative are those

located at the few export ports where GIPSA does onsite original inspection services. GIPSA believes that restricting the current proposed action to only appeal inspections would adversely impact the cost benefits and the flexibility associated with the current proposal. Table 1 below illustrates this point.

TABLE 1.—FULL-GRADE INSPECTION SUMMARY, FY 1994–2001

Year	Original inspections			Reinspections			Appeals
	OA's ¹	GIPSA ²	Total	OA's ¹	GIPSA ²	Total	GIPSA ²
FY 1997	1,828,519	119,907	1,948,426	36,698	4,844	41,542	3,140
FY 1998	1,861,718	117,267	1,918,985	29,012	5,058	34,078	3,443
FY 1999	1,750,211	117,916	1,868,127	26,046	4,529	30,575	3,103
FY 2000	1,717,625	110,114	1,827,739	19,778	4,515	24,293	3,103
FY 2001	1,706,817	102,295	1,809,112	22,073	4,797	26,870	3,105

¹ Total performed by all state and private official agencies.

² Total performed by all GIPSA field offices.

2. Restrict Proposed Action to Reinspections

Licensed inspectors employed by state or private official agencies perform most reinspections. GIPSA only performs reinspections at certain export port locations. GIPSA believes that if the proposed action were limited to reinspections, more applicants for service could potentially benefit than limiting the proposed action to appeal inspections. Some applicants, however, might be placed at a competitive disadvantage because their sales contracts require them to request appeal inspections on some or all original inspection services. Additionally, about ten percent of all reinspections are appealed. If the grading procedures for appeals are different from the preceding reinspection, the review inspection process is not similar for all levels of the review inspection process.

The review inspection process should provide all applicants the same opportunity for inspection services. Reinspection services and appeal inspection services should be similar in scope and effect. For this reason, GIPSA decided to propose the regulatory change that would favorably affect both the reinspection process and the appeal inspection process.

The cost savings of the proposed action on the grain industry could be very positive. Although it is impossible to estimate an exact dollar savings, the time spent waiting for inspection results could be reduced by at least 50 percent and could, in certain circumstances, exceed 90 percent. Since grain elevators often “idle” their load-out operations until the results of a reinspection or appeal are known, domestic shippers

could save several hundred dollars in operation and demurrage costs on an average 100-car unit train. The savings for exporters could reach \$10,000 for some vessels. For example: If elevator X has a fixed operating cost of \$500 an hour and it takes an average of 30 minutes to perform a reinspection or appeal inspection, then each reinspection or appeal will cost the elevator an additional \$250 in down time. If the time required to perform the reinspection or appeal is reduced to 15 minutes, the elevator saves \$125 per inspection due to the more efficient inspection service. These savings could be multiplied if the time saved on performing the reinspections or appeals allows the elevator to avoid or limit demurrage (*i.e.*, a fee assessed to the elevator for failing to complete the loading of a unit train or ship within a specified period). Currently, the demurrage for railcars can range up to \$50 per day per car. The demurrage on export vessels can reach \$10,000 a day.

The potential revenue impact of the proposed action on GIPSA and official agencies should not be significant. In the long run, this proposed rule may encourage slightly more reinspection and appeal inspection services because of the increased efficiencies associated with the proposal. However, GIPSA does not believe that its net revenue will significantly change. GIPSA routinely reviews the agency's revenue and cost of service as part of its ongoing fee review process. If inspection services and revenue from those services change significantly, GIPSA may determine a change in fees is needed and would do so as part of a fee proposal.

Executive Order 12988 and 12898

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have a retroactive effect. This rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administration procedures that must be exhausted prior to any judicial challenge to the provision of this rule.

Pursuant to Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations,” GIPSA has considered potential civil rights implications of this proposed rule on minorities, women, or persons with disabilities to ensure that no person or group will be discriminated against on the basis of race, color, sex, national origin, religion, age, disability, or marital or familial status. The proposed rule will apply in the same manner to all persons and groups whose activities are regulated, regardless of race, gender, national origin, or disability. Preliminary information indicates that the proposal will have no effect on protected populations. GIPSA will make wide distribution of this proposal and will address all comments in the final rulemaking.

Information Collection and Recordkeeping Requirements

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements in Part 800 have been previously approved by OMB and assigned OMB No. 0580–0013.

List of Subjects in 7 CFR Part 800

Administrative practice and procedure, Grains.

PART 800—GENERAL PROVISIONS

For reason set out in the preamble, GIPSA proposes to amend 7 CFR part 800 as follows:

1. The authority citation for part 800 continues to read as follows:

Authority: Pub. L. 94–582, 90 Stat. 2867, as amended (7 U.S.C. 71 *et seq.*).

2. Section 800.125 (b) is revised to read as follows:

§ 800.125 Who may request reinspection services or review of weighing services.

* * * * *

(b) *Kind and scope of request.* A reinspection or review of weighing service is limited to the kind and scope of the original service. If the request specifies a different kind or scope, the request shall be dismissed but may be resubmitted as a request for original services: Provided, however, that an applicant for service may request a reinspection of a specific factor(s), official grade and factors, or official criteria. In addition, reinspections for grade may include a review of any pertinent factor(s), as deemed necessary by official personnel. Official criteria are considered separately from official grade or official factors when determining the kind and scope. When requested, a reinspection for official grade or official factors and official criteria may be handled separately even though both sets of results are reported on the same certificate. Moreover, a reinspection or review of weighing may be requested on either the inspection or Class X weighing results when both results are reported on a combination inspection and Class X weight certificate.

3. Section 800.135(b) is revised to read as follows:

§ 800.135 Who may request appeal inspection services.

* * * * *

(b) *Kind and scope of request.* An appeal inspection service is limited to the kind and scope of the original or reinspection service; or, in the case of a Board Appeal inspection service, the kind and scope of the appeal inspection service. If the request specifies a different kind or scope, the request shall be dismissed but may be resubmitted as a request for original services: Provided, however, that an applicant for service may request an appeal or Board Appeal inspection of a specific factor(s), official grade and factors, or official criteria. In addition, appeal and Board Appeal

inspections for grade may include a review of any pertinent factor(s), as deemed necessary by official personnel. Official criteria are considered separately from official grade or official factors when determining kind and scope. When requested, an appeal inspection for grade, or official factors, and official criteria may be handled separately even though both results are reported on the same certificate. Moreover, an appeal inspection may be requested on the inspection results when both inspection and Class X weighing results are reported on a combination inspection and Class X weight certificate.

(Approved by the Office of Management and Budget under control number 0580–0013)

Dated: August 15, 2002.

Donna Reifschneider,

Administrator.

[FR Doc. 02–21158 Filed 8–20–02; 8:45 am]

BILLING CODE 3410–EN–P

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Chapter VII**

[Docket No. 020725179–2179–01]

Effectiveness of Licensing Procedures for Agricultural Commodities to Cuba

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Request for comments.

SUMMARY: The Bureau of Industry and Security (BIS) is requesting public comments on the effectiveness of its licensing procedures as defined in the Export Administration Regulations for the export of agricultural commodities to Cuba. BIS is required to submit a biennial report to the Congress on the operation of the licensing system for such exports, which was created to implement the Trade Sanctions Reform and Export Enhancement Act of 2000. To help make this assessment, BIS is seeking public comments on the effectiveness of these measures.

DATES: Comments must be received by September 20, 2002.

ADDRESSES: Written comments (three copies) should be sent to Sheila Quartermann, Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044. Comments may also be e-mailed to Brian Nilsson, Office of Strategic Trade and Foreign Policy Controls, at BNilsson@bis.doc.gov.

FOR FURTHER INFORMATION CONTACT: Joan Roberts, Director, Foreign Policy

Controls Division, Bureau of Industry and Security, Telephone: (202) 482–5400. Additional information on BIS procedures is available under the heading “Trade Sanctions Reform and Export Enhancement Act” at www.bis.doc.gov. Copies of this material may also be requested by contacting the Office of Strategic Trade and Foreign Policy Controls.

SUPPLEMENTARY INFORMATION: The current procedures of the Bureau of Industry and Security (BIS) for authorizing the export of agricultural commodities to Cuba are set forth in § 740.18 of the Export Administration Regulations (EAR). Under the provisions of section 906(c) of the Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA) (Pub. L. 106–387), as amended, BIS must submit a report to the Congress on the operation of the licensing system under Section 906 of TSRA for the preceding two-year period. This report is to include the number and types of licenses applied for, the number and types of licenses approved, the average amount of time elapsed from the date of filing of a license application until the date of its approval, the extent to which the licensing procedures were effectively implemented, and a description of comments received from interested parties about the extent to which the licensing procedures were effective, after holding a public 30-day comment period. This notice serves as public notice to solicit such comments.

Parties submitting comments are asked to be as specific as possible. All comments received by the close of the comment period will be considered by BIS in developing the report to Congress. All information relating to the notice will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, BIS requires written comments. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying.

Copies of the public record concerning these regulations may be requested from: Bureau of Industry and Security, Office of Administration, U.S. Department of Commerce, Room 6883, 1401 Constitution Avenue, NW., Washington, DC 20230; (202) 482–0637. This component does not maintain a separate public inspection facility. Requesters should first view BIS’s website (which can be reached through www.bis.doc.gov). If requesters cannot

access BIS's website, please call the number above for assistance.

James J. Jochum,

Assistant Secretary for Export Administration.

[FR Doc. 02-21161 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-33-U

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

Consolidation of Customs Drawback Centers

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations to reflect a planned closure of the Customs Drawback Centers located at the ports of Boston, Massachusetts; Miami, Florida; and New Orleans, Louisiana. Because of a sustained decrease in the number of drawback claims and the amount of drawback payments, Customs is proposing a consolidation of the Drawback Program. The closing of the three Drawback Centers is part of the planned consolidation and is intended to promote operational efficiency in the processing of drawback claims.

DATES: Comments must be received on or before September 20, 2002.

ADDRESSES: Written comments (preferably in triplicate) may be submitted to the U.S. Customs Service, Office of Regulations & Rulings, Attention: Regulations Branch, 1300 Pennsylvania Avenue NW., Washington, DC 20229. Submitted comments may be inspected at the U.S. Customs Service, 799 9th Street, NW., Washington, DC, during regular business hours. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572-8768.

FOR FURTHER INFORMATION CONTACT: Sherri Hoffman, U.S. Customs Service, Entry and Drawback Management, (202) 927-0300.

SUPPLEMENTARY INFORMATION:

Background

Consolidation of Drawback Centers

Since 1996, Customs has recognized a decrease in both the number of drawback claims and the amount of drawback payments. To verify these trends, and to determine how to most efficiently operate the Drawback

Program, Customs conducted an internal evaluation of the program. Customs also retained the services of an independent contractor to review the Drawback Program to ensure that the agency's findings were valid.

The findings of both the agency-led review and the independent contractor's assessment indicated the benefits of consolidating the processing of drawback claims by reducing the number of Drawback Centers.

In a Notice to Congress on March 12, 2001, filed in accordance with 19 U.S.C. 2075, Customs proposed the closure of four Drawback Centers. The Senate Finance and House Ways and Means Committees concurred with the proposal for consolidation, but with the recommendation that only three Drawback Centers be eliminated and the San Francisco Drawback Center remain operational. The Commissioner of Customs concurred with this recommendation and it was proposed to phase-in the closure of the Drawback Centers located at the ports of Boston, MA; Miami, FL; and New Orleans, LA. The remaining five Drawback Centers, located at the ports of New York, NY/ New York, NJ; Houston, TX; Chicago, IL; Los Angeles, CA; and San Francisco, CA would remain operational.

Closing of Drawback Centers To Be Phased-In

To assist the remaining five Drawback Centers in accommodating an increased number of drawback claims, it is proposed to phase-in the closing of the three Drawback Centers. If, after further consideration and review of any comments submitted in response to the solicitation of comments set forth in this document, Customs decides to adopt as a final rule these proposed changes, it is proposed to phase-in the closing of the Drawback Centers as follows:

(1) The first Drawback Centers to close would be the centers at the ports of Boston, Massachusetts and New Orleans, Louisiana. These two centers would close 30 days from the date a final rule adopting these proposed changes is published in the **Federal Register**. At that time, drawback claims would no longer be accepted at the Boston or New Orleans Drawback Centers, and claims would be required to be filed at one of the five remaining Drawback Centers. Drawback claims submitted to the Boston or New Orleans Drawback Centers after this date would be rejected. Once rejected, it would be the responsibility of the claimant to ensure timely filing of the drawback claim at one of the five remaining Drawback Centers. Customs personnel at the ports of Boston and New Orleans

would continue to process drawback claims that were submitted prior to commencement of this first phase-in period, for a period of 12-months. After this time, all remaining claims filed at the Boston Drawback Center prior to commencement of this first phase-in period, that have not been liquidated and require Customs review, would be forwarded to the New York/Newark Drawback Center for final processing. All remaining claims that were filed at the New Orleans Drawback Center prior to commencement of this first phase-in period, that have not been liquidated and require Customs review, would be forwarded to the Houston Drawback Center for final processing.

(2) The third Drawback Center to close would be the one located at the port of Miami, Florida. This center would close 180 days from the date a final rule adopting these proposed changes is published in the **Federal Register**. At that time, drawback claims would no longer be accepted at the Miami Drawback Center, and claims would be required to be filed at one of the five remaining Drawback Centers. Drawback claims submitted to the Miami Drawback Center after this date would be rejected. Once rejected, it would be the responsibility of the claimant to ensure timely filing of the drawback claim at one of the five remaining Drawback Centers. Customs personnel at the port of Miami would continue to process drawback claims that were submitted prior to commencement of this second phase-in period, for a period of 12-months. After this time, all remaining claims filed at the Miami Drawback Center prior to commencement of this second phase-in period, that have not been liquidated and require Customs review, would be forwarded to the Chicago Drawback Center for final processing.

Claimant Requirements To File in Designated Alternate Drawback Centers

In order to file a drawback claim at one of the five remaining Drawback Centers, a claimant would be required to possess either a district permit for the location at which the claim will be filed or a national permit. Claimants are reminded that a national permit requires use of the Automated Broker Interface of Customs Automated Commercial System when filing drawback claims. Claimants must ensure that all permit, license and bond requirements are met in accordance with the regulations. See parts 111 and 113 of the Customs Regulations.

Maintenance of Drawback Information

Throughout the staged consolidation period, claimants would be required to provide Customs with advance notification of any changes in the information provided regarding a drawback claim. This notification must be provided in accordance with part 191 of the Customs Regulations (19 CFR part 191).

Explanation of Amendments

Section 101.3(b)(1) of the Customs Regulations lists the Customs ports of entry. Eight ports are denoted with an asterisk that designates their status as a "Drawback unit/office." This document proposes to amend § 101.3(b)(1) to delete the asterisks in § 101.3(b)(1) next to the port listings for Boston, Miami and New Orleans.

Comments

Before adopting this proposal as a final rule, consideration will be given to any written comments timely submitted to Customs, including comments on the clarity of this proposed rule and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4 of the Treasury Department Regulations (31 CFR 1.4), and § 103.11(b) of the Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 799 9th Street, NW., Washington, DC.

The Regulatory Flexibility Act and Executive Order 12866

Although this document is being issued with notice for public comment, because it relates to agency management and organization, it is not subject to the notice and public procedure requirements of 5 U.S.C. 553. Accordingly, this document is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Agency organization matters, such as this proposed closing of three Customs Drawback Centers, are not subject to Executive Order 12866.

Drafting Information

The principal author of this document was Ms. Suzanne Kingsbury, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Customs ports of entry.

Proposed Amendments to the Regulations

For the reasons stated above, it is proposed to amend part 101 of the Customs Regulations (19 CFR part 101) as follows:

PART 101—GENERAL PROVISIONS

1. The general authority citation for part 101 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

Section 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b;

* * * * *

2. In § 101.3, the table in paragraph (b)(1) is amended by removing the plus sign in the "Ports of entry" column before the column listings for "Miami" under the state of Florida, "New Orleans" under the state of Louisiana, and "Boston" under the state of Massachusetts.

Robert C. Bonner,

Commissioner of Customs.

Approved: August 15, 2002.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 02-21111 Filed 8-20-02; 8:45 am]

BILLING CODE 4820-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket Numbers 98N-0496 and 00N-1633]

RIN 0910-AB24 and 0910-AB95

Import for Export; Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Subsequent Export; Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission Into the United States; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rules; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of two proposed rules. One proposed rule, which appeared in the **Federal Register** on November 24, 1998 (63 FR 64930), would have established reporting and recordkeeping requirements for certain products that

are imported into the United States for further processing or incorporation into products that are then exported. The second proposed rule, which appeared in the **Federal Register** on January 22, 2001 (66 FR 6502), would have established requirements for marking imported food that has been refused entry into the United States for safety reasons. FDA is withdrawing these proposed rules due to recent changes in Federal law.

DATES: The proposed rules are withdrawn August 21, 2002.

FOR FURTHER INFORMATION CONTACT:

Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

SUPPLEMENTARY INFORMATION: On November 24, 1998, FDA published a proposed rule in the **Federal Register** (63 FR 64930) that would have established reporting and recordkeeping requirements for certain products that are imported under section 801(d)(3) and (d)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(d)(3) and (d)(4)). These sections of the act allowed the importation of certain unapproved or otherwise noncompliant products or articles provided that those products or articles are further processed or incorporated into other products and then exported from the United States.

On January 22, 2001, FDA and the Department of the Treasury jointly prescribed a proposed rule in the **Federal Register** (66 FR 6502) that would have allowed FDA to require food importers or consignees to mark imported foods if, for safety reasons, FDA had refused to allow such foods to enter the United States. The mark would have stated, "UNITED STATES REFUSED ENTRY," and the proposed rule would have established the mark's size and required the mark to be affixed on packing containers holding the refused food and on invoices, bills of lading, and any other documentation accompanying the food when it is exported from the United States.

We received comments on both rules and also held public meetings to discuss the proposed rule on the marking of refused food imports. After reviewing the comments, we wrote and intended to issue final rules in 2002.

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The new law contains provisions that change the legal context of the two proposed FDA regulations

described previously in this document. For example, the new law gives FDA express authority to require marking on any food product that had been refused admission into the United States whereas the proposed rule would have required marking on food refused admission for safety reasons only.

The new law also significantly revises section 801(d)(3) of the act; it prescribes new reporting requirements that differ from those in the FDA proposed rule.

Because of the changes brought about by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA is withdrawing both proposed rules. FDA will consider whether new rulemakings or other actions are necessary to implement the new statutory requirements.

Dated: August 13, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02-21264 Filed 8-20-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 02N-0241]

Amendment of Regulations on Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutrition; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the **Federal Register** of August 12, 2002 (67 FR 52429). The document proposed to amend FDA's regulations to change the labeling requirements concerning aluminum in small volume parenterals and pharmacy bulk packages used in total parenteral nutrition. The document was published with an inadvertent error. This document corrects that error.

DATES: Submit written or electronic comments by October 28, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments at <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the

docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Doris B. Tucker, Office of Policy, Planning, and Legislation (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 02-20300, appearing on page 52429 in the **Federal Register** of Monday, August 12, 2002, the following correction is made:

1. On page 52429, in the third column, in the seventh line “§ 201.323©” is corrected to read “§ 201.323(c)”.

Dated: August 15, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02-21265 Filed 8-20-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 343

[Docket No. 77N-0941]

RIN 0910-AA01

Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph, and Related Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the tentative final monograph (TFM) for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products to include ibuprofen as a generally recognized safe and effective analgesic/antipyretic active ingredient for OTC use. FDA is also proposing to amend its regulations to include consistent allergy warnings for OTC IAAA drug products containing nonsteroidal anti-inflammatory active ingredients. These proposals are in response to a citizen petition (Ref. 1) and to a comment submitted in response to that petition (Ref. 2) and are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written or electronic comments by November 19, 2002. Submit written or electronic comments

on the agency's economic impact determination by November 19, 2002. Please see section XII of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Ida I. Yoder, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

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I. Background

Ibuprofen is benzenecarboxylic acid, α -methyl-4-(2-methylpropyl), (\pm), a member of the propionic acid class of nonsteroidal anti-inflammatory drugs (NSAIDs). The commercially available drug is a racemic mixture of two optical isomers (S-[+] and R-[-] ibuprofen). The racemic mixture is recognized in the U.S. Pharmacopeia (U.S.P.) (Ref. 3). Ibuprofen has been available as a prescription drug for the treatment of osteoarthritis and rheumatoid arthritis at a dose of 1,200 to 3,200 milligrams (mg) per (/) day since 1974 in the United States and since 1969 in the United Kingdom. Ibuprofen has also been marketed by prescription and OTC in numerous countries throughout the world (Ref. 4).

Safety and effectiveness data submitted to the agency to support the approval of the OTC marketing of a 200-mg ibuprofen tablet were considered by the Arthritis Advisory Committee (AAC)

at its August 18, 1983, meeting. Based on the available data, the AAC concluded that a 200-mg ibuprofen product could be used safely and effectively OTC, without the supervision of a physician (Ref. 5). It has been available on the OTC market for use in adults and children 12 years and older since 1984 through the new drug application (NDA) process. It is marketed at a 200-mg dosage strength, for the relief of minor aches and pains and for fever reduction. A single OTC dose is 200 to 400 mg with a maximum daily dose of 1,200 mg.

The AAC suggested warnings and precautions that it believed should appear in labeling to alert individuals to certain risks, especially those individuals who should not use ibuprofen without the supervision of a physician. The AAC was concerned that the promotion of OTC ibuprofen not counteract a warning regarding ibuprofen's cross-reactivity with aspirin (Ref. 5). The agency's approved labeling for ibuprofen includes warnings for aspirin sensitive individuals and people taking other OTC pain reliever/fever reducer products (Ref. 6).

On October 17, 1983, a citizen petition (Ref. 7) was submitted that requested the agency to reopen the administrative record for OTC IAAA drug products to amend the proposed monograph to include ibuprofen as an internal analgesic ingredient in a 200-mg tablet with a maximum 1,200-mg total daily dose. The agency denied the petition on May 18, 1984 (Ref. 8) for several reasons, one of which (use for a material time and to a material extent) is discussed in section III.A of this document.

In the **Federal Register** of November 16, 1988 (53 FR 46204), the agency published a TFM to establish conditions under which OTC IAAA drug products are generally recognized as safe and effective, and not misbranded. The TFM proposed acetaminophen, aspirin, carbaspirin calcium, choline salicylate, magnesium salicylate, and sodium salicylate as generally recognized as safe and effective IAAA active ingredients for OTC use and appropriate labeling for OTC drug products containing these ingredients. Ibuprofen was not discussed in the TFM.

Subsequent to the TFM, the agency received a citizen petition (Ref. 1) requesting that the TFM be amended to include racemic ibuprofen in an oral dosage form, as a single active ingredient. The petition recommended a minimum effective dose of 200 mg ibuprofen for use by adults and children 12 years and older. The petition requested the same indications as

proposed for other monograph IAAA active ingredients in § 343.50(b)(1) (21 CFR 343.50(b)(1)): "For the temporary relief of minor aches and pains associated with a cold, sore throat, headache, toothache, muscular aches, backache, premenstrual and menstrual cramps (dysmenorrhea), and for the minor pain from arthritis, and to reduce fever."

The petition requested warnings specific for the OTC use of ibuprofen, including the following warning, in this form, or in a different format conveying the same information:

ASPIRIN SENSITIVE PATIENTS:

Although this product does not contain aspirin, it may cause a severe reaction in people allergic to aspirin. Do not take ibuprofen if you have had any of the following reactions to any pain reliever/fever reducer:

- allergic reaction
- shock
- hives
- difficulty breathing
- asthma
- swelling

If you are under a doctor's care for any serious condition, consult a doctor before taking this product. As with aspirin and acetaminophen, if you have any condition which requires you to take prescription drugs or if you have had any problems or serious side effects from taking any nonprescription pain reliever, do not take this product without first discussing it with your doctor. **IF YOU EXPERIENCE ANY SYMPTOMS WHICH ARE UNUSUAL OR SEEM UNRELATED TO THE CONDITION FOR WHICH YOU TOOK IBUPROFEN, CONSULT A DOCTOR BEFORE TAKING ANY MORE OF IT.** Although ibuprofen is indicated for the same conditions as aspirin and acetaminophen, it should not be taken with them except under a doctor's direction. Do not combine this product with any other ibuprofen-containing product.

The petition also suggested the following directions for use:

Adults: Take 200 mg every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 200 mg, 400 mg may be used but do not exceed 1,200 mg in 24 hours, unless directed by a doctor. The smallest effective dose should be used. Take with food or milk if occasional and mild heartburn, upset stomach, or stomach pain occurs with use. Consult a doctor if these symptoms are more than mild or if they persist. **Children:** Do not give this product to children under 12 years of age except under the advice and supervision of a doctor.

The petition asserted that ibuprofen has been marketed for a material time and to a material extent. To support this statement, the petition presented information indicating that from May 1984 (when ibuprofen first became available OTC in the United States) through 1996 over 90 billion 200-mg tablet doses were sold (Ref. 1). The petition noted that more than 20 companies now market OTC ibuprofen drug products and provided information to show that the sale of OTC ibuprofen in the United States is comparable to that of aspirin and acetaminophen. Thus, the petitioner said, given the enormous volume of sales and more than 13 years of marketing, ibuprofen has been available as an OTC drug product for a material time and to a material extent, is now generally recognized as safe and effective, and is no longer a new drug. The petition did not request monograph status for ibuprofen for children under 12 years of age.

The petition (Ref. 1) included a summary of safety and effectiveness data (through 1982) previously submitted to FDA to support the prescription-to-OTC switch of ibuprofen. That summary included effectiveness data for ibuprofen for analgesic (dysmenorrhea, dental, musculoskeletal, postpartum and postsurgical pain, and headache), antipyretic, and anti-inflammatory use and a safety overview of specific organ systems, special populations, and postmarketing data. The petition (Ref. 1) also included the results from a search of the worldwide medical literature from 1983 through August 1996 of adverse events associated with ibuprofen, mostly in the OTC dosage range.

The published studies and case reports included in the petition involved mainly OTC doses of ibuprofen (less than or equal to 1,200 mg/day) for an OTC-indicated duration (less than 10 days use for pain, or 3 days for fever) that occurred in generally healthy individuals, 12 years of age or older. The agency's comments on the citizen petition are on file in the Dockets Management Branch (Ref. 9). The petitioner subsequently submitted additional information in support of ibuprofen's safety profile (Ref. 10), which included publications from 1990 through 1998, generated from a number of databases.

The agency also received a comment opposing the petition's request to include ibuprofen in the TFM (Ref. 2). The petition, related correspondence, additional information, and the opposing comment are on public

display in the Dockets Management Branch (see **ADDRESSES**).

II. Comment in Opposition to the Citizen Petition

One comment (Ref. 2), opposing the petition's request, stated there is: (1) A lack of a general recognition of safety and effectiveness of all oral ibuprofen dosage forms, (2) a significant potential for use of OTC ibuprofen products at prescription dosage levels, and (3) a continued need for adverse event reporting and other marketing controls. Therefore, the comment contended, ibuprofen (200 mg) should remain subject to the NDA process.

The comment suggested that allowing marketing of ibuprofen (200 mg) in any "suitable" oral dosage form (as provided for in the TFM) creates a potential for consumer harm. As examples, the comment mentioned several risks if ibuprofen would be included in the monograph: (1) Changes in product composition and manufacturing methods that would not be subject to prior FDA review, and (2) possible misuse of ibuprofen products due to the concurrent marketing of ibuprofen suspensions (one marketed under a monograph for adults and the other marketed under the new drug approval process and labeled for children).

The comment also criticized the data included in the petition. The comment observed that although data on adverse events in prescription dosages is relevant to the consideration of whether an ingredient is appropriate for inclusion in the monograph, the petition submitted only information on adverse effects at OTC doses. The comment asserted that ingestion of larger doses (2,400 to 3,600 mg) has not been seen due to the relative expense of the OTC tablets. The comment contended that the lowered prices that would result from monograph status of ibuprofen (200 mg) could increase the potential for harm because prescription ibuprofen users may be enticed to switch to OTC drug products and self-medicate at prescription dose levels without a doctor's supervision. The comment did not provide any data to support its assertions.

The agency agrees with the opposing comment (Ref. 2) that ibuprofen is not generally recognized as safe and effective in all dosage forms. For instance, ibuprofen in suspension formulation for adult use has not been marketed OTC, and children's formulations have been marketed OTC less than 5 years. Thus, these formulations are not generally recognized as safe and effective for OTC use. In some studies evaluating the

effectiveness of ibuprofen, capsule formulations were used as a means of blinding the studies. However, ibuprofen has been marketed OTC for adult use almost entirely in tablet formulations (i.e., tablets, caplets, and gelcaps (a tablet dosage form)) throughout its marketing history. Thus, current evidence for ibuprofen to be generally recognized as safe and effective for OTC use is only sufficient for tablet formulations. This proposal does not include liqui-gel formulations (ibuprofen solubilized in a gel matrix).

The comment raised a concern about the potential for OTC ibuprofen to be used at prescription-dose levels. Currently approved NDA and abbreviated new drug application (ANDA) labeling for OTC ibuprofen drug products contains directions for appropriate OTC dosing. Products marketed under an OTC drug monograph will contain the same directions. Further, both the NDA/ANDA and the proposed monograph labeling alert consumers of the hazards associated with improper use and when to seek the advice of a physician. Given that the comment did not include any data to support its concern, the agency finds no basis to believe that the potential for misuse of these OTC ibuprofen drug products will be greater if their marketing status is changed from an NDA/ANDA to OTC drug monograph.

The agency appreciates the comment's concern for the need for continued adverse event reporting and other marketing controls. The safety of ibuprofen has been monitored since it was first marketed in the United States under the new drug approval process (as a prescription drug in 1974 and as an OTC drug in 1984) and as a generic drug (for prescription use in 1985 and for OTC use in 1986). The agency monitors the quality of products marketed under OTC drug monographs through its current good manufacturing practice regulations in part 211 (21 CFR part 211) and its inspection authority. Based on the available data, the agency finds the safety profile of ibuprofen to be comparable to that of other OTC internal analgesics (e.g., aspirin and acetaminophen) that have been proposed as generally recognized to be safe for OTC use.

During ibuprofen's extensive OTC marketing history significant formulation and manufacturing issues have not arisen. The agency does not anticipate any potential problems if ibuprofen, in specific tablet formulations, is included in the monograph for adult use. Specifications for ibuprofen tablets are recognized in

the U.S.P. (Ref. 3). Although there is some degree of risk associated with the use of any OTC drug, whether marketed through the NDA/ANDA process, as a generic drug, or under an OTC drug monograph, the agency believes ibuprofen 200 mg in a tablet dosage form for adult use has been marketed safely OTC for a sufficient time and extent that it can be generally recognized as safe and effective for OTC use.

III. The Agency's Evaluation of the Citizen Petition

A. Use for a Material Time and to a Material Extent

In 1984, the agency denied a petition (Ref. 7) to include ibuprofen in the OTC IAAA monograph because the request was for a new dosage strength (200 mg) which the agency determined had not been used to a material extent and for a material time in the United States and, thus, was considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). The petitioner had contended that ibuprofen had been available in the United States since 1974 as a prescription drug with more than 18.8 billion cumulative 400-mg doses of the drug distributed worldwide through August 1982, and that the drug is currently the fourth largest prescription drug by volume in the United States. In its denial letter (Ref. 8), the agency pointed out that experience with ibuprofen at prescription strength is pertinent to the drug's safety, but such experience cannot support general recognition that the product, at a different strength and daily dose, can be used safely and effectively by the patient alone. The agency concluded that the petition ignored the lack of experience with the proposed single 200-mg tablet dose as an OTC drug product.

Since that time, the current petition (Ref. 1) points out that from May 1984 (when ibuprofen 200-mg first became available OTC in the United States) through 1996 over 90 billion 200-mg tablet doses were sold. That number has substantially increased since 1996. The agency has determined that ibuprofen's 17 years of OTC marketing with over 100 billion doses of 200-mg tablets sold shows that the drug at this dosage and in this dosage form as an internal analgesic and antipyretic has been used for a material time and to a material extent to qualify it for inclusion in an OTC drug monograph.

B. Safety

1. Preclinical

a. *Toxicity.* The toxicity of ibuprofen has been extensively studied in a number of animal species (Refs. 11 and 12) and well characterized. The LD₅₀ in the mouse was 800 mg/kilogram (kg) orally and 320 mg/kg intraperitoneally. In rats, the LD₅₀ was 1,600 mg/kg orally and 1,300 mg/kg subcutaneously. In dogs, adverse effects were observed after a single oral dose of 125 mg/kg. There were no apparent ill effects after a single 20 or 50 mg/kg dose. Ibuprofen in lethal doses depressed the central nervous system of rodents, and was ulcerogenic in rodents and nonrodents.

Newly weaned male and female rats were given 180, 60, 20, and 7.5 mg/kg/day ibuprofen by oral gavage for 26 weeks (Ref. 12). Rats receiving ibuprofen grew normally except for male rats receiving the 180-mg/kg/day dose which gained significantly less weight than controls. When examined hematologically in the final week of dosing, both males and females on the 180 mg/kg/day dose were anemic as evidenced by low erythrocyte counts, hemoglobin concentrations, and hematocrits. Significant increases in the weights of the kidney, liver, and spleen occurred in both sexes. Histologic examination of the tissues revealed no significant changes except for one male and three female rats in the 180-mg dose group (10 animals/sex/group) that had intestinal ulcers.

In a followup experiment (Ref. 12) to determine if the changes observed in the 26-week study were reversible, male and female rats were given 180, 60, and 20 mg/kg/day for 13 weeks. The day after dosing ended, half the animals in each group were sacrificed and the rest were kept undosed for 3 weeks. Generally, the results from this experiment were supportive of the 26-week study. Males given 180 mg/kg/day had enlarged kidneys, spleen, and testes. A dose-dependant enlargement of the kidney occurred in females. An enlargement of the liver and ovaries occurred in females on 180 mg/kg/day, and of the spleen and ovaries in females on 60 mg/kg/day. None of the enlarged organs were histologically abnormal. These changes were found to be reversible 3 weeks after the end of dosing.

No significant hematological or biochemical alterations were observed in dogs (two dogs/sex/group) given 16, 4, or 2 mg/kg/day ibuprofen (administered as two doses 6 hours apart) for 26 weeks (Ref. 12). In the eighth week of dosing, female dogs in the high-dose group showed gross signs

of gastrointestinal (GI) disturbance characterized by frequent vomiting, diarrhea (with occasional passage of fresh blood), and loss of blood. Occult blood was irregularly detected in fecal samples obtained from all dogs in the high-dose group from day 8 on. At autopsy, organ weights were normal and pathologic changes were limited to ulcerative lesions of the GI tract.

The effects of ibuprofen on reproduction have been studied in rats and rabbits (Ref. 12). Rats were administered 180, 60, 20, or 7.5 mg/kg/day ibuprofen on days 1 through 20 of pregnancy. All litters were of normal size and weight. No difference in the incidence of fetal malformations was found between the treated and control groups.

A reproduction study in rabbits (Ref. 12) at doses of 60, 20, or 7.5 mg/kg/day was conducted on days 1 through 29 of pregnancy. Female rabbits given 60 mg/kg/day had fewer live fetuses per litter than did controls, but there was no significant difference in the number of dead and resorbed rabbits per litter. However, there was a reduction in the ratio of implants to corpora lutea, which suggested that the decrease in live litter size was due to interruption of early pregnancy. The average fetal weight was normal. At the lower doses, the litter size was unaffected. Apart from four young in one litter (60 mg/kg/day) with multiple malformations characteristic of cyclopia, there was no consistent pattern of dose-related malformations. The authors concluded that ibuprofen is not teratogenic but may reduce fertility by affecting early pregnancy at the high dose.

The labeling of ibuprofen drug products currently marketed under an NDA/ANDA includes the general pregnancy/breast-feeding warning in § 201.63(a) (21 CFR 201.63(a)) advising that a health professional should be consulted before use. It also includes a statement like that required for aspirin drug products in § 201.63(e), which warns that it is especially important not to use the product during the third trimester of pregnancy because it could cause problems in the unborn child and complications during delivery. The agency is proposing to expand the warning in § 201.63(e) to include ibuprofen. (See section V, number 1 of this document.)

b. *Pharmacokinetics.* Ibuprofen's mode of action is not completely understood, but it may be related to its ability to inhibit prostaglandin synthetase (Ref. 13). Following oral dosing, ibuprofen has been found in synovial fluid, which is the proposed site of action for ibuprofen in patients

with rheumatoid arthritis (Ref. 14). The pharmacologic activity of ibuprofen has been attributed mostly to the S-[+]-enantiomer (Refs. 15 and 16). After administration of racemic ibuprofen, the inactive R-[-]-enantiomer is slowly and incompletely (60 percent) converted to the biologically active S-[+]-enantiomer, primarily through both presystemic and systemic chiral inversion (Refs. 17, 18, and 19).

The pharmacokinetics of ibuprofen have been well documented (Ref. 20). The absorption of orally administered ibuprofen is rapid and approximately 80 percent of the dose is absorbed from the GI tract. Peak plasma levels in humans are reached between 45 and 90 minutes after administration of a single oral dose on an empty stomach, depending upon the formulation (Ref. 21). The extent of absorption is unchanged when ibuprofen is taken with meals (Ref. 22).

Following oral administration, the apparent plasma volume of distribution has been reported to be between 0.1 to 0.2 liter (L)/kg, which approximates plasma volume and suggests minimal tissue binding is present (Refs. 23 and 24). Ibuprofen is extensively bound (more than 98 percent) to whole human plasma and purified serum albumin at therapeutic concentrations, and may participate in plasma protein binding displacement reactions (Refs. 25 and 26). The apparent volume of distribution, based on total concentration, increases significantly with dose, but there is no attendant change in free drug volume of distribution (Ref. 27). The protein binding of ibuprofen is similar between normal individuals and people with osteoarthritis and rheumatoid arthritis and is not influenced by age or gender (Refs. 28 and 29).

Plasma concentrations of ibuprofen appear to decline in a biphasic manner with a plasma half-life of 2 to 4 hours for the racemate (Ref. 20). Ibuprofen is metabolized via oxidation by the cytochrome P-450 enzyme CYP 2C9 to form two inactive metabolites, hydroxy- and carboxypropyl-phenylpropionic acid (Refs. 30 and 31). These metabolites (or their glucuronide conjugates) are excreted in the urine and account for about 50 to 60 percent of the oral dose administered (Refs. 32 and 33). Less than 10 percent of the drug is excreted in urine unchanged (Ref. 32). The remainder is eliminated in the feces, as metabolites and unabsorbed drug. Excretion of ibuprofen is essentially complete within 24 hours following oral administration of a single dose (Ref. 33). While total clearance may be affected by age, no dosage adjustment is needed in the elderly (Ref.

34). Ibuprofen does not appear in the breast milk of mothers to any appreciable extent (i.e., < 0.0008 percent of the plasma level) (Ref. 35).

Ibuprofen is neither an inducer or an inhibitor of cytochrome P-450 mediated metabolism. At doses above those recommended for OTC use (1,200 mg daily, in divided doses), ibuprofen may decrease the renal excretion of some drugs due to ibuprofen's ability to interfere with renal prostaglandin synthesis necessary for normal renal function. This interference in the renal elimination of other drugs can be estimated by following the net reduction in creatinine clearance. Ibuprofen can cause an increase in blood pressure in hypertensive patients being treated with diuretics alone or diuretics combined with other agents (Ref. 36).

2. Clinical Data

The petition (Ref. 1) and a subsequent submission (Ref. 10) provided extensive published clinical data on the safety of OTC use of ibuprofen. The data provide a safety profile typical of other OTC drugs in the NSAID class.

a. *Gastrointestinal.* The GI tract is one of the major organ systems commonly affected by NSAID-induced drug toxicity. This resulted in a GI warning in the prescription labeling for these drugs (Refs. 37 and 38). At the August 18, 1983, AAC meeting, data submitted in support of the NDA for ibuprofen 200 mg to be marketed as an OTC drug product suggested that, of all NSAIDs available at that time, ibuprofen caused the least amount of GI irritation (Ref. 39).

Additional support in favor of ibuprofen's overall gastric tolerability was generated in a recent study by Moore et al. (Ref. 40), which evaluated the tolerability of ibuprofen (1,200 mg/day) and acetaminophen (up to 3 grams (g)/day) to that of aspirin (up to 3 g/day). This study was a large, blinded, randomized, multicenter, 7-day analgesic study conducted in France in 8,677 adults with mild to moderate pain due to a variety of conditions. Although the incidence for significant (serious, severe, or moderate) adverse events (including all body systems) for the ibuprofen treated group (13.7 percent) was comparable to that of the acetaminophen treated group (14.5 percent), both drugs were shown to be significantly better tolerated than aspirin (18.7 percent; $p < 0.001$ via a one-sided 96.5 percent confidence interval (CI)). A total of six subjects reported having GI bleeds during this study, four from the acetaminophen group and two from the aspirin group, one of whom developed peptic ulcer.

Overall, treatment with ibuprofen was associated with fewer significant adverse GI events than aspirin ($p < 0.001$) or acetaminophen ($p < 0.02$). The incidences of abdominal pain and dyspepsia were both significantly lower in the ibuprofen group as compared with the aspirin ($p < 0.001$) or acetaminophen ($p < 0.02$) groups. Although this study was designed to approximate the general population who would use OTC doses and durations of these three analgesics, its selection criteria prohibited any individual with known risk factors for GI bleeding from participating. Thus, selection bias may have been introduced and resulted in a lower incidence of GI adverse events than what may be seen in the general population at risk.

In a retrospective, nested, case-controlled study of Medicaid enrollees, Griffin et al. (Ref. 41) compared the relative risk (RR) for the development of peptic ulcer disease (PUD) in 1,415 subjects 65 years and older who were current nonaspirin NSAID users to nonusers. Eighty-three of the 1,415 subjects who were hospitalized due to PUD during the period studied were identified as having been exposed to OTC doses (1,200 mg) of ibuprofen. The overall RR for the development of PUD in this group was found to be 2.3 (95 percent CI: 1.8 to 3.0). Further examination by dose revealed that in 70 subjects exposed to doses less than 2,400 mg ibuprofen the RR for the development of PUD was 2.2 (95 percent CI: 1.7 to 2.9), and in 13 subjects exposed to 2,400 mg or greater the RR increased to 3.3 (95 percent CI: 1.7 to 6.5).

Bradley et al. (Ref. 42) conducted a 4-week, double-blind, randomized trial in 184 subjects comparing the effectiveness and safety of the maximum approved OTC daily dose of 1,200 mg of ibuprofen (number of subjects (n) = 62) to that of a prescription dose of 2,400 mg/day (n = 61), and to 4,000 mg/day of acetaminophen (n = 59) for the treatment of osteoarthritis. While there were no significant differences in the number of side effects reported during this study, the study demonstrated a trend towards a dose-dependent increase in minor GI adverse events (nausea and dyspepsia) associated with higher doses of ibuprofen (1,200 mg/day: 7/62 or 11.3 percent; versus 2,400 mg/day: 14/61 or 23 percent). In addition, two subjects treated with 2,400 mg/day of ibuprofen became positive for occult blood while participating in the study.

Although these studies (Refs. 41 and 42) demonstrate that a dose-dependent relationship exists for ibuprofen-

induced gastrotoxicity, the number of subjects exposed to OTC doses of ibuprofen (1,200 mg or less a day) is too small to draw valid conclusions. Further, the study results may also be confounded since the studies did not control for other risk factors (i.e., smoking, alcoholism, concomitant use of corticosteroids and anticoagulants, advanced age, prior history of PUD, or deteriorated general health status) which are known to increase the risk of developing GI bleeding while using NSAIDs. In addition, the results of the retrospective study (Ref. 41) may be biased because the exposure data from that study were generated from records of prescriptions written for both the study and control populations rather than what was actually used by the subjects.

In a matched, case-controlled, international study of upper gastrointestinal bleeding (UGIB), Kaufman et al. (Ref. 43) evaluated the association between regular and occasional NSAID use and the risk of major UGIB in subjects hospitalized with their first major UGIB. Subjects were asked about their history of NSAID use, and details of timing, duration, frequency, and the daily dose of each episode of use. The focus of the data analysis was on NSAID use in the week immediately before the day of onset of bleeding. Exposure was defined as any use in the week before the index day. No evidence of an association of gastric bleeding with either regular use (n = 9; RR: 1.0 [95 percent, 0.4 to 2.6]) or occasional use (n = 14; RR 1.1 [95 percent, 0.5 to 2.4]) of ibuprofen was identified in this study. Among the cases of gastric bleeding, the median ibuprofen dose was 2,332 mg. The RR for developing a duodenal bleed with regular use (n = 7) of ibuprofen was 2.4 (95 percent, 0.5 to 11), the median daily ibuprofen dose ingested was 1,074 mg.

Strom et al. (Ref. 44) did a retrospective, case-controlled study in a Medicaid population generated database and evaluated the risk of developing GI bleeding associated with the use of OTC-simulated doses of naproxen sodium (600 mg/day or less) versus ibuprofen (1,200 mg/day or less). (At the time of the study, naproxen sodium was not yet approved for OTC use.) Although this study demonstrated that the overall incidence of UGIB associated with either the use of naproxen sodium [0.026 percent (95 percent CI, 0.017 percent to 0.038 percent)] or ibuprofen [0.012 percent (95 percent CI, 0.008 percent to 0.017 percent)] at simulated OTC doses was relatively low, the RR for developing an UGIB was approximately twofold higher for the

naproxen sodium cohort [2.0 (95 percent CI, 1.1 to 3.8)] as compared to the ibuprofen cohort. The study also showed that the RR for developing UGIB is increased in subjects who ingest multiple NSAIDs at OTC doses [4.1 (95 percent CI, 1.2 to 13.8)].

Endoscopic data (Refs. 45 and 46) demonstrated that while ibuprofen produced less GI mucosal toxicity or gastric injury than other NSAIDs, low doses of ibuprofen produced lesions in some subjects. In a study by Bergmann et al. (Ref. 45), endoscopic lesions of 12 healthy volunteers were evaluated after the administration of single doses of ketoprofen (25 mg), ibuprofen (200 mg), and aspirin (500 mg), and rated on a scale of 0 to 4. Endoscopic scores for ketoprofen were comparable to those for ibuprofen. After a single dose of ibuprofen 200 mg, eight subjects had endoscopic scores of 0, one had a score of 1, and three had scores of 2. For ketoprofen, nine subjects had a score of 0, two had a score of 2, and one had a score of 3.

Lanza (Ref. 46) conducted an endoscopic study of normal volunteers without histories of PUD. Subjects were prohibited from using alcohol and other NSAIDs for the week before and during the study. Ingestion of 1,200 mg/day of ibuprofen for 7 days produced a gastric injury score of 0.46 (on a scale of 0 to 4) and a 0 ulcer incidence rate in the 13 subjects studied. However, an increase in the ibuprofen dose to 1,600 mg/day for 7 days under the same conditions produced ulcers in 5 out of the 55 (9.1 percent) subjects studied, and an injury score of 1.24.

A chromium 51-labeled fecal blood loss study (Ref. 47) indicated that after 5 days of treatment with either ibuprofen 1,500 mg/day, aspirin 1,500 mg/day, lysine clonixinate 375 mg/day, or placebo, the fecal blood loss in subjects treated with ibuprofen was significantly less than the aspirin treated group. Nevertheless, treatment with ibuprofen lead to a small increase in mean daily blood loss of +0.52 milliliter (mL)/day.

These studies indicate that ibuprofen, at OTC doses, has a low level of GI toxicity but is not entirely devoid of such toxicity. The agency believes that even this low level of toxicity could increase the risk of GI bleeding in people who have other risk factors for developing GI bleeding. Therefore, the agency is proposing including a warning in the labeling of OTC ibuprofen to alert individuals at risk for GI problems associated with the use of the product. The warning would include: "Ask a doctor before use if you have: • stomach problems that last or come back, such as

heartburn, upset stomach, or pain • ulcers • bleeding problems".

b. *Renal.* NSAIDs affect renal physiology by inhibiting cyclo-oxygenase and the synthesis of vasodilatory prostaglandins resulting in acute intrarenal hemodynamic changes that can cause reversible deterioration in the renal function of susceptible individuals (Ref. 48). Thus, in individuals with decreased renal blood flow, impaired renal function, or hypovolemia, the use of NSAIDs can produce an increase in serum creatinine concentrations and a decrease in creatinine clearance that may progress to acute renal failure, but which is reversible by stopping the drug (Ref. 48). This has necessitated precaution statements in the labeling of prescription NSAIDs directed at the management of patients who use these drugs, despite having prostaglandin-dependent states such as renal disease, heart failure, liver dysfunction, concomitant diuretic therapy, and advanced age that put them at risk for developing this type of nephrotoxicity (Ref. 38). Although the class labeling for prescription NSAIDs also mentions idiosyncratic forms of nephrotoxicity, such as papillary necrosis, acute interstitial nephritis, and nephrotic syndrome that may develop with long-term use of these drugs, these cases are usually not associated with any identifiable risk factor and are rare in occurrence (Ref. 49).

The petition (Ref. 1) included a summary package that was prepared for the August 18, 1983, AAC meeting in which ibuprofen 200 mg was considered for OTC marketing. The summary included safety data generated from clinical trials and supportive evidence from a review of then-published case reports of ibuprofen-associated nephrotoxicity. The summary concluded that although ibuprofen does cause cyclo-oxygenase mediated renal toxicity like other members of the NSAID class, the reversibility of this condition is dependent upon its recognition and the discontinuation of the drug, particularly when it occurs in those at risk, such as the chronically ill or the elderly (Ref. 39).

In support of ibuprofen's renal safety profile, four studies (Refs. 50 through 53) that evaluated the prostaglandin-mediated effects of OTC doses of ibuprofen ($\leq 1,200$ mg a day) on renal function were reviewed. In a crossover study, Farquhar (Ref. 50) evaluated the renal effects of ibuprofen (1,200 mg daily) and acetaminophen (4 g daily) versus a placebo in 12 healthy men ($n = 6$) and women ($n = 6$) who were subjected to progressive renal stress.

Subjects were on a low-sodium diet, on limited exercise, and given a drug or placebo for 3 days and the morning of day four. On day four, the participants were subjected to treadmill exercise, in the heat, to cause dehydration. The combined stressors caused decreases in effective renal plasma flow, glomerular filtration rate (GFR), and sodium excretion. Baseline GFR (range 118 to 123 mL/minute (min) decreased to 73 ± 5 , 78 ± 4 , and 82 ± 5 mL/min, post-exercise, in the ibuprofen, acetaminophen, and placebo groups, respectively, with a significantly greater decrease in GFR for ibuprofen than placebo ($p < 0.05$). The decrease in GFR for the acetaminophen group was not significantly different from placebo. The authors attributed the lower GFR that occurred in the ibuprofen arm of the study to renal prostaglandin inhibition by the drug.

In a randomized, disease-controlled study, Ciabattini et al. (Ref. 51) evaluated the prostacyclin-mediated effects on GFR and renal blood flow of 20 women with chronic glomerular disease versus 19 normal healthy control subjects following 7 days of treatment with ibuprofen (1,200 mg daily) versus sulindac (400 mg daily). In the 10 subjects with renal insufficiency who were given ibuprofen, the serum creatinine level was increased by about 40 percent and the creatinine and para-aminohippurate clearances were decreased by 28 ± 7 and 35 ± 8 percent, respectively, during treatment ($p < 0.01$). Renal function returned to baseline values after ibuprofen was discontinued, although the serum creatinine and creatinine clearance were still significantly altered up to 5 days after ibuprofen was stopped.

Welton et al. (Ref. 52) evaluated the renal effects of ibuprofen (800 mg three times daily), piroxicam (20 mg daily), and sulindac (200 mg twice daily) in an 11-day, randomized, triple crossover study of 12 women with asymptomatic, mild, stable, chronic renal failure with serum creatinine ranging from 130 to 270 micromoles (μmol)/L. Although all the subjects were able to complete courses of treatment with piroxicam and sulindac, three subjects developed acute decreases in renal function with an elevation in their renal parameters that met the study criteria for stopping (defined as an increase in serum creatinine of 130 μmol /L or more, or a serum potassium value of more than 6 millimole/L (mmol/L)) by the eighth day of treatment with ibuprofen. When these three subjects were rechallenged with ibuprofen, 400 mg three times a day, two again developed acute deterioration of renal function. The authors

concluded that a brief course of nonprescription ibuprofen may result in the precipitous decrease in the renal function of people with asymptomatic, mild, chronic renal failure.

In contrast, Furey et al. (Ref. 53) did a 7-day, double-blind, randomized study comparing the renovascular effects of ibuprofen (400 mg three times daily) versus that of aspirin (650 mg three times daily) and acetaminophen (650 mg three times daily) in 25 elderly subjects with mild renal insufficiency, and hypertension controlled with thiazide diuretics. Although the mean baseline serum creatinine levels for all three treatment groups were comparable, the mean baseline serum creatinine clearances were higher in both the acetaminophen (78.9 ± 8.3 mL/min) and aspirin (67.1 ± 6.4 mL/min) treatment groups as compared to the ibuprofen group (56.3 ± 5.3 mL/min). On analysis, this was not found to be statistically different. This study failed to demonstrate any statistically significant changes in the five renal parameters (serum creatinine, creatinine clearance, blood urea nitrogen (BUN), serum potassium and sodium) evaluated in any of the three treatment groups.

The three studies by Farquhar (Ref. 50), Ciabattini et al. (Ref. 51), and Welton et al. (Ref. 52) demonstrated that, at an OTC dose of ibuprofen (1,200 mg daily), hemodynamic changes in the kidney do occur in subjects with prostaglandin-dependent states, which can lead to diminished renal function. The inability of the study by Furey et al. (Ref. 53) to demonstrate any significant deterioration in any of the renal parameters studied may be due to the fact that the subjects who participated in this study may not have had severe enough renal disease as manifested by the mildly elevated range of their baseline mean serum creatinine from 1.4 ± 0.08 mg/deciliter (dL) to 1.5 ± 0.07 mg/dL to demonstrate ibuprofen's prostaglandin-dependent renal effects. Thus, despite their histories of hypertension and the concomitant use of diuretics, these subjects may also have had adequate renal reserves to compensate for any ibuprofen-mediated decreases in their renal function.

The largest study involving an OTC dose of ibuprofen that included monitoring of renal function was the 4-week study by Bradley et al. (Ref. 42). This study compared the effectiveness of low-dose (1,200 mg daily) and high-dose (2,400 mg daily) ibuprofen and acetaminophen (4,000 mg daily) in the treatment of osteoarthritis in 184 subjects. Side effects were similar in all three groups. The serum creatinine level increased by more than $17 \mu\text{mol/L}$ (0.2

mg/dL) in four of the subjects receiving low-dose ibuprofen, six receiving high-dose ibuprofen, and one receiving acetaminophen. As a group, the serum creatinine concentration increased only slightly ($2.7 \mu\text{mol/L}$) in the high-dose ibuprofen group ($p = 0.04$), but there was no increase in the low-dose group. Although this trial is the only study which compared a low-dose (i.e., OTC dose) to a high-dose (i.e., prescription-strength dose) ibuprofen and could possibly be interpreted as a dose-ranging study for the renal effects of ibuprofen-mediated prostaglandin inhibition, the subjects who were entered into this trial were healthy with a mean age of 55.7 ± 13.7 to 57.2 ± 11.7 years. Exclusion criteria prohibited participation by subjects with medical conditions that contraindicated the use of the study medications. Thus, the study subjects were not reflective of the population identified at risk for developing this type of nephrotoxicity.

The petition included numerous case reports (Refs. 54 through 61) of renal failure associated with the use of OTC doses of ibuprofen in people with normal renal function. Four cases (Refs. 54 through 57) described the syndrome of acute flank pain with reversible renal failure following short-term doses of 1,200 mg, or less, of ibuprofen. One (Ref. 54) of these four cases was confounded by the concomitant use of alcohol, and one (Ref. 55) used alcohol and acetaminophen, both of which can cause nephrotoxicity. Four reports (Ref. 58 through 61) described cases of idiosyncratic drug-induced types of renal failure. One of the cases (Ref. 61) discussed a case of idiosyncratic hypersensitivity reaction in an elderly man who experienced acute renal failure twice; once after taking ibuprofen orally and, again, a few years later, after using a topical formulation of ibuprofen. Renal function returned to normal in all eight people after medical therapy. The agency is aware of additional case reports of patients who developed renal toxicity after taking ibuprofen (Refs. 62 through 66).

In 1996, the National Kidney Foundation published a position paper in which it recommended that consumer labeling of OTC analgesic drug products contain warnings directed to the population at risk for the development of nephrotoxicity associated with the use of these products (Ref. 67). These recommendations were based on the review of a database that contained 556 articles on aspirin, acetaminophen, aspirin/acetaminophen combinations, and NSAID-related renal disease by an ad hoc group of expert investigators and

clinicians. This committee suggested the following consumer warning for OTC NSAID-containing products:

DO NOT TAKE THIS PRODUCT WITHOUT PHYSICIAN SUPERVISION IF: (1) You are allergic to aspirin; (2) you are under a physician's care for asthma or stomach problems (such as heartburn); (3) you take diuretic medicine; (4) you have heart disease, high blood pressure, kidney disease, or liver disease; (5) you are over 65 years of age.

The information contained in the literature review and case reports submitted in support of this petition confirms that OTC doses of ibuprofen can exert a variety of renal adverse effects, particularly in those who are predisposed by prostaglandin-dependent states. Although the sporadic nature of the idiosyncratic drug-induced type of ibuprofen nephrotoxicity makes it impossible to predict which group of individuals is at risk for developing this type of adverse event, this is not the case with individuals who experience prostaglandin-driven hemodynamic changes in renal function. The latter, if recognized, is reversible following discontinuation of the drug. Thus, based on the information reviewed, the agency concurs with the recommendations made by the National Kidney Foundation that the consumer labeling for OTC ibuprofen should have a warning directed at those at risk for the development of acute renal failure associated with the use of the product. The agency is proposing a warning that includes: "Ask a doctor before use if you have: • high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age".

c. *Hepatic.* The petition (Ref. 1) contained only one case report (Ref. 68) from the literature of biopsy-proven drug-induced hepatitis that occurred in a person taking 1,200 mg daily ibuprofen and cefadroxil. The authors concluded that the liver lesion was induced by drug hypersensitivity. The supplemental submission (Ref. 10) included one case report (Ref. 69) of drug-induced vanishing bile duct syndrome secondary to ibuprofen. Similarly, the authors of this report concluded that the reaction was induced by a drug hypersensitivity.

In a retrospective, crossover cohort study, Garcia-Rodriguez et al. (Ref. 70) evaluated the risk of developing serious, acute, noninfectious liver injury associated with the use of NSAIDs. One of the 16 subjects was identified as having NSAID-induced hepatitis: A 93-year-old male who developed cholestatic jaundice after taking 1,200

mg of ibuprofen along with other hepatotoxic drugs. Causality could not be directly associated with ibuprofen in this case due to the concomitant use of other hepatotoxic drugs.

In a review of FDA postmarketing data of NSAID-induced hepatotoxicity, Katz et al. (Ref. 71) noted that while ibuprofen is known to cause idiosyncratic metabolic toxicity of the liver, ibuprofen and ketoprofen were found to have the lowest reported calculated incidences of hepatotoxicity (0.55 percent and 0.56 percent respectively) of all NSAIDs evaluated at that time. Due to the limitations of FDA's reporting requirements, the authors were unable to estimate separately the incidence of this phenomena associated with OTC doses of ibuprofen. Given the available information, the agency sees no need to propose a hepatitis warning at this time.

d. *Blood*. Three case reports from the literature described hematological events attributed to ibuprofen (Refs. 72, 73, and 74). Two of these (Refs. 72 and 73) involved individuals taking OTC doses of ibuprofen who developed thrombocytopenia and white-cell aplasia with bone marrow plasmacytosis. The duration of ibuprofen use was not stated in the second case report. The third individual (Ref. 74), taking an undisclosed dose of ibuprofen (by prescription), developed Pelger-Huet syndrome due to a complement-dependent immunoglobulin G (IgG) antibody that prevented bone marrow production of myeloid stem cells. Ibuprofen is known to reversibly inhibit platelet aggregation (Ref. 75). Further, ibuprofen has been shown to potentiate the effects of warfarin. As a result, the agency believes consumers who are taking anticoagulants should be alerted to check with a health professional before taking ibuprofen because of the potential for bleeding. Thus, the agency is proposing a warning that includes: "Ask a doctor or pharmacist before use if you are: • taking a prescription drug for anticoagulation (blood thinning)".

e. *Immune system*. Ibuprofen has been associated with some hypersensitivity reactions. The petition (Ref. 1) included 14 case reports (Refs. 76 through 86) from the worldwide literature that described hypersensitivity and anaphylactic reactions to ibuprofen. The reports of ibuprofen-associated hypersensitivity (Refs. 76 through 80) included six individuals with underlying histories of asthma (one (Ref. 78) of whom also had a known allergy to aspirin). Three of the individuals with asthma died following hypersensitivity reactions that were

attributed to ibuprofen (Refs. 76, 77, and 78). One report (Ref. 86) included five patients with Sjögren's syndrome who developed symptomatic drug allergies after taking ibuprofen.

Hypersensitivity reactions were also reported in one individual (Ref. 80) with general allergies (including a known aspirin sensitivity), in one individual (Ref. 82) with systemic lupus erythematosus, and in three individuals (Refs. 83, 84, and 85) with no apparent underlying illnesses (one (Ref. 84) had taken aspirin just prior to the reaction). The petition also included an abstract of a report of challenge testing with ibuprofen (Ref. 87) in 42 people with histories of allergies to various analgesic agents. Five people experienced anaphylactic reactions to incremental doses of up to 500 mg of ibuprofen. Eleven of 33 subjects had similar reactions to aspirin. The agency is proposing an "Allergy alert" warning and additional allergy warning statements for all OTC drug products containing NSAID IAAA active ingredients. (See section IV of this document.)

f. *Nervous system*. The petition (Ref. 1) included 20 literature citations (Refs. 82 and 88 through 106) that described 21 individuals with aseptic meningitis associated with the use of ibuprofen. Twelve of these individuals (Refs. 82, 88 through 95, 98, and 100) had underlying histories of systemic lupus erythematosus or other immune disorders, 3 (Ref. 96) had histories of arthritis, 1 (Ref. 97) had a history of spontaneous recurrent aseptic meningitis, and 5 (Refs. 100 through 104) reportedly had no underlying medical problems. The supplemental submission (Ref. 10) included several review articles (Refs. 107 through 110) that described the spectrum of central nervous system side effects reported to be associated with NSAIDs, as well as case reports (Refs. 111 through 115) of aseptic meningitis associated with the use of a variety of NSAIDs. Although there has been an increase in availability and use of NSAIDs in general, the overall number of aseptic meningitis cases reported to be associated with the use of these agents since 1978 is only about 35. Most of the case reports (Refs. 111, 112, and 114) involved individuals with underlying collagen vascular disorders (i.e., systemic lupus erythematosus and rheumatoid arthritis). Several cases (Refs. 111, 113, and 115) established direct causality by histories of positive dechallenge-rechallenge with the suspected NSAID. While other NSAIDs were sometimes implicated, ibuprofen was the most commonly reported. The

agency does not believe a nervous system warning is needed at this time.

g. *Skin*. There were a total of seven case reports (Refs. 116 through 122) and two articles (Refs. 123 and 124) on the results of provocative skin testing with ibuprofen. The seven case reports describe episodes of fixed drug reactions (Ref. 116), erythema nodosum (Ref. 117), a bullous drug eruption (Ref. 118), various cases of urticaria (Ref. 119), exacerbations of psoriasis (Refs. 120 and 121), and the occurrence of dermatitis herpetiformis (Ref. 122). The doses of ibuprofen involved in these cases, when reported, were 800 mg daily. The two articles (Refs. 123 and 124) described the results of provocative testing with a variety of drugs including ibuprofen. Of the 169 patients tested, 11 had positive skin reactions to ibuprofen. As stated above, the agency is proposing allergy warnings for OTC drug products containing NSAIDs. (See section IV of this document.)

h. *Special senses*. There were three case reports (Refs. 125, 126, and 127) and one adverse event, which occurred during a clinical trial (Ref. 128), that mentioned ibuprofen's effects on the visual parameters. The reports involved macular hemorrhage in people with age-related maculopathy (Ref. 126), vortex keratopathy (Ref. 127), iridocyclitis (Ref. 125), and depressed contrast sensitivity (Ref. 128) associated with total daily doses of ibuprofen ranging from 800 to 2,400 mg. Given the available information, the agency sees no need to propose a special senses warning at this time.

3. Spontaneous Reporting System (SRS) and Adverse Event Reporting System (AERS) Data

The petition analyzed adverse event data from the FDA SRS for all single-ingredient OTC ibuprofen drug products marketed in the United States for the time period from May 1984 through July 1996. Adverse reaction reports associated with a generic OTC ibuprofen drug product marketed under an ANDA or prescription ibuprofen drug products used at OTC doses were excluded from this analysis. A total of 8,168 case reports associated with 16,627 adverse events in the SRS database attributed to the use of single-ingredient, nongeneric OTC ibuprofen were thus identified. The total number of adverse events was greater than the total number of case reports because some case reports included more than one adverse reaction associated with the use of the drug.

The petitioner screened the electronic records of all case reports for confounding factors. Reports were

considered confounded if they included the coadministration of at least one other medication (drug confounder), the administration of ibuprofen in a dose greater than 1,200 mg/day (dose confounder), the administration of ibuprofen for more than 10 days (duration confounder), or if the subject was less than 12 years of age (age confounder). Reports with missing or unreliable data were included in the analysis. Screening for confounders yielded 3,540 nonconfounded case

reports which generated 6,197 adverse events. Case reports were then reviewed to identify serious reports associated with OTC ibuprofen. Of the 3,540 nonconfounded case reports, 592 were considered to be serious in nature. FDA's definition of a serious outcome is an event that results in death or hospitalization, is life threatening, produces permanently disability or congenital anomaly, or one in which medical intervention is required. However, the case report forms for these

serious reactions were not included in the petition. The petition (Ref. 1) submitted information on case reports from the SRS associated with the use of OTC ibuprofen, reported by COSTART (Coding Symbols for Thesaurus of Adverse Reaction Terms) body system terminology. The information is summarized in table 1 of this document and represents the number of case reports that included at least one adverse event associated with the COSTART term.

TABLE 1.—SUMMARY OF CASES ASSOCIATED WITH THE USE OF OTC IBUPROFEN IN THE FDA SPONTANEOUS REPORTING SYSTEM FROM MAY 1984 THROUGH JULY 1996 (REF. 1)

COSTART Term	No. of Cases Reported	No. of Nonconfounded Cases	No. of Serious Nonconfounded Cases
Allergic reaction/ anaphylaxis	461	261	72
Body as a whole	3,686	1,786	236
Cardiovascular system	795	293	127
Digestive system	2,445	916	236
Endocrine system	32	12	8
Hematological/lymphatic systems (blood)	679	141	92
Liver	165	35	9
Metabolic and nutritional system	757	176	71
Musculoskeletal system	163	49	7
Nervous system	1,447	577	101
Respiratory system	629	250	81
Skin and appendages	1,339	589	71
Special senses	479	188	29
Urogenital system	716	176	61

The 592 serious nonconfounded case reports included 7 deaths associated with the use of OTC ibuprofen (2 GI, 1 hematological effects, 2 anaphylaxis, 1 miscarriage, and 1 in utero exposure resulting in the postpartum death of an encephalic infant). As shown above in table 1 of this document, the largest number of adverse events involved the GI system. Of the 236 nonconfounded serious case reports related to the GI system, 94 were GI hemorrhage, 52 were various ulcerations, 32 were melena, 25 were abdominal pain, and 20 were hematemesis. This additional evidence supports the need for a GI tract warning in the consumer labeling of OTC ibuprofen drug products.

FDA queried its AERS database for reports of renal failure in adults, over 16 years of age, associated with the use of OTC doses of ibuprofen for the period extending from the time of initial approval for OTC marketing (May 18, 1984) through August 10, 1999 (Ref. 129). For completeness, a search of the AERS database was also done for reports of renal failure in people 16 years of age and under. Fourteen cases of renal failure were identified in this population. In 8 of the 14 cases, a children's suspension formulation was used while, in the remaining 6 cases, 200-mg tablets were reportedly ingested.

After excluding cases involving prescription dosages, overdoses, or duplication, there were a total of 80 cases of renal failure in adults over 16 years of age associated with the use of 1,200 mg, or less, of ibuprofen a day. Although 37 of these 80 cases had positive dechallenges with the discontinuation of ibuprofen (which is supportive of the reversibility of this drug-induced adverse event), 9 cases required dialysis treatment. Of these 80 cases, 56 were severe enough to require hospitalization, with 9 reported deaths, out of which 5 listed ibuprofen-induced renal failure as a contributing cause of death. Hypertension (16), pre-existing renal insufficiency (8), diabetes (7), other cardiac problems (8), alcoholism (3), and hepatic disease (2) were some of the most commonly concurrent medical disorders reported. In addition, 15 people were reported to have been taking diuretics prior to developing renal failure. These cases further support the need for consumer labeling directed at those individuals with predisposing medical conditions for the development of ibuprofen-induced prostaglandin-dependent renal toxicity. (See section III.B.2.b of this document.)

4. American Association of Poison Control Center (AAPCC) Data

The petition (Ref. 1) also included data on ibuprofen from the Toxic Exposure Surveillance System (TESS) collected by the AAPCC from 1987 to 1996. During that time, TESS reported only 9 fatalities from 163,948 OTC ibuprofen exposures compared to 450 fatalities from 312,618 acetaminophen exposures, and 401 fatalities from 153,495 aspirin exposures. The supplemental submission (Ref. 10) included additional information on the nine deaths, reports of seven additional deaths related to OTC ibuprofen in 1997, and three other deaths related to OTC or prescription-strength ibuprofen that occurred in 1996.

Of these 19 deaths, 14 were classified as intentional suicides. One person ingested 165 tablets of 200-mg strength ibuprofen and the other 13 ingested other drugs in combination with OTC ibuprofen. Of the remaining five cases, one was classified as a therapeutic error in a person with a history of alcoholism and hepatic disease waiting for a liver transplant, who reportedly took "excessive" amounts of acetaminophen and ibuprofen for pain. This person's death was attributed to chronic hepatic failure associated with ethanol and

acetaminophen toxicity, chronic pancreatitis, and gastritis.

Another case was reported as intentional misuse in a patient with a history of chronic alcoholism, cirrhosis, and portal hypertension who developed acute liver failure following the chronic use of ibuprofen and acetaminophen. Another case of reported intentional misuse involved a patient with a history of drug abuse who reportedly ingested 27 tablets containing 100 mg propoxyphene napsylate and 650 mg acetaminophen and 50 tablets of ibuprofen (strength not specified) over a 16- to 48-hour period. The remaining two cases were listed as adverse drug reactions in young children. Thus, a large majority of the deaths were suicidal overdoses or intentional abuse associated with the concomitant use of other drugs, and should not be directly attributed to ibuprofen. A few of the cases could have been due to allergic reactions related to ibuprofen use. An allergy warning is required to appear in the labeling of OTC ibuprofen drug products marketed under an NDA/ANDA to alert consumers of that risk.

5. Drug-Drug Interactions

The petition (Ref. 1) included eight journal articles (Refs. 53 and 130 through 135) that described clinical trials involving a variety of antihypertensive agents (i.e., calcium channel blockers, angiotensin converting enzyme inhibitors, and triamterene-hydrochlorothiazide) in chronically treated and elderly

hypertensive patients with renal insufficiency who took OTC doses of ibuprofen. The studies did not demonstrate any diminished antihypertensive effectiveness when these drugs were coadministered with ibuprofen. This is in contrast to the diminution in the effectiveness of a variety of antihypertensive medications such as beta-blockers, ACE inhibitors, hydralazine, and diuretic agents in patients who use prescription doses of NSAIDs (Ref. 136).

6. Tentative Conclusion on the Safety of Ibuprofen

Based on the evaluation of available information, the agency concludes ibuprofen is generally recognized as safe for OTC use by adults and children 12 years of age and older, if the labeling includes appropriate warnings and directions for use. The agency is proposing to include warnings to alert individuals of the potential for renal and GI problems associated with the use of ibuprofen. For consistency in labeling, the agency is also proposing to include the same allergy alert warning statements in the labeling of all OTC NSAID products.

C. Effectiveness

The reports of clinical effectiveness trials submitted in the petition (Ref. 1) compared OTC doses of ibuprofen to aspirin, acetaminophen, and/or codeine-containing analgesic compounds. The petition identified a number of double-blind, randomized clinical trials, either placebo or active controlled. Most of the

studies are generally applicable to the indications proposed in § 343.50 of the TFM for other OTC internal analgesic/antipyretic drug products (e.g., dental pain, pain of arthritis, dysmenorrhea, headache, and sore throat). Nineteen studies (Refs. 137 through 155) were placebo-controlled, and the reports concluded that ibuprofen, at the OTC doses studied, was a more effective analgesic agent than placebo. The authors of these studies (Refs. 137 through 155) and three active-controlled trials (Refs. 156, 157, and 158) also reported that, at the OTC doses studied, ibuprofen was either comparable to or more effective than aspirin, acetaminophen, and various strengths of codeine-containing analgesics or other NSAIDs tested. The pain models included in the studies were dental, headache, episiotomy, sore throat, and dysmenorrhea. One report (Ref. 159) described the results of two randomized, double-blind, parallel studies that compared the antipyretic effectiveness of ibuprofen to aspirin in adults, which showed effectiveness of both the 200- and 400-mg doses of ibuprofen.

The only dosage forms used in the trials and identified in the reports were tablets, caplets, and capsules. Some of the reports did not identify the dosage form. Table 2 of this document summarizes the placebo-controlled and active-controlled trials the agency reviewed to demonstrate the effectiveness of OTC doses of ibuprofen for various pain and fever models.

TABLE 2.—TRIALS TO DEMONSTRATE THE EFFECTIVENESS OF IBUPROFEN FOR VARIOUS PAIN AND FEVER MODELS

Investigator(s) (reference number)	Type of Pain Measured	Dosage Form	Treatment ² (dosage in mg)	Reported Results
Cooper (137)	Dental	Tablets	I 400; AP 600; AP300 + C 30; AP 600 + C 60; P	I more effective than AP 600, AP 300 + C 30, and P (p values not given)
Cooper (138)	Dental	Tablets	I 400; C 60; A 650; A 650 + C 60; I 400 + C 60; P	I 400 more effective than A (p<0.05) and C (p<0.001); I + C more effective than A + C (p<0.05)
Cooper (139)	Dental	N.S. ¹	I 200; AP 650; P	I more effective than P (p<0.05); I comparable to AP
Cooper (140)	Dental	N.S. ¹	I 200; I 400; AP 1000; P	I 200 and I 400 comparable to AP; all more effective than P (p values not given)
Cooper (141)	Dental	N.S. ¹	I 200; I 400; AP 1000; P	I 200 and I 400 comparable to AP; all more effective than P (p values not given)
Cooper (142)	Dental	N.S. ¹	I 200; AP 650; I 200 + AP 650; P	I more effective than AP (p<0.05) and P (p<0.025); I + AP more effective than AP (p<0.05) and P (p value not given)
Cooper et al. (143)	Dental	N.S. ¹	I 400; AP 1000; P	I more effective than AP (p<0.05) and P (p<0.001)
Forbes et al. (144)	Dental	Capsule	I 400; AP 600; AP 600 + C 60; K 10; K 20; P	I, K 10 and K 20 not significantly different; I more effective (p<0.05) than AP and AP + C; all more effective than P (p<0.01)

TABLE 2.—TRIALS TO DEMONSTRATE THE EFFECTIVENESS OF IBUPROFEN FOR VARIOUS PAIN AND FEVER MODELS—Continued

Investigator(s) (reference number)	Type of Pain Measured	Dosage Form	Treatment ² (dosage in mg)	Reported Results
Forbes et al. (145)	Dental	Capsule	I 400; A 650; B 5; B 10; B 25; P	I more effective (p<0.01) than A, B 5, and B 10; I comparable to B 25; all more effective than P (p<0.01 to p<0.05)
Forbes et al. (146)	Dental	Capsule	I 400; A 650; B 10; B 25; B 50; B 100; P	I more effective than A (p<0.01); B 25 and B 100 more effective than I (p<0.01); all more effective than P (p<0.01)
Giles et al. (147)	Dental	N.S. ¹	I 200; C 15; I 200 + C 15; A 600; P	I comparable to A and I + C, and more effective (p<0.05) than C and P; I + C comparable to A and more effective (p<0.05) than C and P
Jain et al. (148)	Dental	Tablet	I 100; I 200; I 400; A 650; P	I (all doses) and A more effective than P (p<0.001); no consistent significant difference among active groups
Mehlich et al. (149)	Dental	Tablet or caplet	I 400; AP 1000; P	I more effective (p<0.001) than AP and P; AP more effective than P (p<0.001)
Ngan et al. (150)	Dental	Capsule	I 400; A 650; P	I more effective (p<0.05) than A and P; A more effective than P (p<0.05)
Diamond (151)	Headache	Tablet	I 400; I 800; A 650; P	No statistically significant difference among active drugs; all active drugs more effective than P (p = 0.02 to p = 0.018)
Schachtel et al. (152)	Headache	Capsule	I 400; AP 1000; P	I more effective (p<0.01) than AP and P; AP more effective than P (p<0.01)
Nebe et al. (153)	Headache	Tablet	I 200; A 500; P	I at least as effective as A; I and A more effective than P (p = 0.002 and 0.046, respectively)
Schachtel et al. (154)	Episiotomy	N.S. ¹	I 400; AP 1000; P	I more effective (p<0.05) than AP and P; AP more effective than P (p<0.05)
Schachtel et al. (155)	Sore throat	N.S. ¹	I 400; AP 1000; P	I more effective (p<0.01) than AP and P; AP more effective than P (p<0.01)
Habib et al. (156)	Dental	Enteric coated tablets.	I 400; DHC 30; A 600 + CA 60 (soluble); AP 1000 + C 16 + CA 60 (dispersible)	I comparable to AP + C + CA (p>0.05) and A + CA (p>0.05); All more effective than DHC (p<0.001 in each case)
Noyelle et al. (157)	Headache	Capsule	I 400; A 650; A 1000; AP 1000	I comparable to A 1000; I more effective (p>0.01) than A 650 and AP 1000
Milsom and Andersch (158).	Dysmenorrhea	N.S. ¹	I 400; N 250; AP 500	I reduced pain (p<0.05); I more effective than N and AP (no p value given); N and AP no significant reduction in pain
Gaitonde et al. (159)	Fever	Capsule	I 200; A 300 (Study 1), I 400; A 600 (Study 2)	I 200 and I 400 effective as antipyretics; I 200 comparable to A 300 (p>0.05); I 400 comparable to A 600 (p>0.05)

¹ N.S. = Not stated.² A = aspirin; AP = acetaminophen; B = bromfenac; CA = caffeine; C = codeine; DHC = dihydrocodeine; I = ibuprofen; K = ketorolac; N = naproxen sodium; P = placebo.

The agency has evaluated the reports and agrees that the studies support the effectiveness of ibuprofen as an OTC drug product for a variety of pain and fever models. These studies support the general recognition of racemic ibuprofen as an effective internal analgesic/antipyretic drug at a minimum dose of 200 mg every 4 to 6 hours.

D. Labeling

Internal analgesic/antipyretic drug products containing ibuprofen have been marketed for OTC use under the NDA/ANDA process for many years with indications for use and warnings similar to those proposed in § 343.50(b) and (c) of the TFM for other OTC internal analgesic/antipyretic drug products. In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA

established a standardized format and standardized content for the labeling of OTC drug products (§ 201.66 (21 CFR 201.66)). Table 3 of this document shows parts of the approved labeling for currently marketed OTC ibuprofen drug products for adults under the NDA process, using the new “Drug Facts” labeling format in § 201.66.

BILLING CODE 4160-01-S

Table 3.—Current (NDA) Ibuprofen Labeling using the Format in § 201.66

Drug Facts	
Active Ingredient (in each tablet)	Purpose
Ibuprofen (200 mg).....	Pain reliever/fever reducer
Uses	
<ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ minor pain of arthritis ■ headache ■ backache ■ menstrual cramps ■ the common cold ■ muscular aches ■ toothache ■ temporarily reduces fever 	
Warnings	
Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: <ul style="list-style-type: none"> ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.	
Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer	
Ask a doctor before use if you have: <ul style="list-style-type: none"> ■ stomach pain ■ problems or serious side effects from taking pain relievers or fever reducers 	
Ask a doctor or pharmacist before use if you are: <ul style="list-style-type: none"> ■ under a doctor's care for any serious condition ■ taking any other drug ■ taking any other product that contains ibuprofen or any other pain reliever/fever reducer 	
When using this product take with food or milk if stomach upset occurs	
Stop use and ask a doctor if: <ul style="list-style-type: none"> ■ an allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ stomach pain or upset gets worse or lasts ■ redness or swelling is present in the painful area ■ any new symptoms occur 	
If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> ■ adults: <ul style="list-style-type: none"> ■ take 1 tablet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 tablet, 2 tablets may be used ■ do not exceed 6 tablets in 24 hours unless directed by a doctor ■ the smallest effective dose should be used ■ children under 12 years: ask a doctor 	
Other information ■ store at 20 - 25°C (68 - 77°F). ■ avoid high humidity and excessive heat above 40°C (104°F).	
Inactive ingredients [list inactive ingredients in alphabetical order]	
Questions or Comments? Call xxx xxx xxxx	

In addition to the indications approved for currently marketed OTC ibuprofen 200-mg products, the proposed labeling in the TFM for other internal analgesic/antipyretic drug products includes an indication for sore throat in § 343.50(b)(1). The agency will discuss the proposed sore throat indication for all of these drug products in a future issue of the **Federal Register**. Currently marketed ibuprofen for adult use does not include an indication for sore throat. Thus, the agency is not including a sore throat claim for ibuprofen in this current proposal.

The approved labeling of OTC drug products containing aspirin, ibuprofen, ketoprofen, and naproxen sodium as active ingredients, marketed under the NDA/ANDA process, includes an "Allergy alert" warning and additional allergy warning statements under the headings "Do not use" and "Stop use and ask a doctor if" (see table 3 of this document). These allergy warning statements are similar to the allergy warnings requested in the petition. Proposed labeling for OTC drug products containing aspirin ingredients in § 343.10(b) and (c) (21 CFR 343.10(b) and (c)) of the TFM also includes an allergy warning in § 343.50(c)(1)(iv), which states: "Do not take this product if you are allergic to aspirin or if you have asthma unless directed by a doctor." For those products containing salicylate active ingredients in § 343.10(d) through (f) the proposed warning in § 343.50(c)(1)(vi) of the TFM states: "Do not take this product if you are allergic to salicylates (including aspirin) unless directed by a doctor."

The Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products (the Panel) proposed allergy warnings for aspirin. In discussing the safety of OTC aspirin use (42 FR 35346 at 35397 through 35399, July 8, 1977), the Panel concluded that in sensitive individuals aspirin produces allergic type reactions, that include: (1) Rash, (2) swelling, (3) hives and giant hives, (4) shortness of breath to severe asthma attacks, and (5) anaphylactic shock involving laryngeal swelling and a precipitous drop in blood pressure. The Panel provided a detailed discussion of the importance of an aspirin hypersensitivity warning (42 FR 35346 at 35397). The Panel noted that the incidence of hypersensitivity reactions (dermal and pulmonary) has been estimated to be about 0.2 percent of the general population, but that as much as 20 percent is found in some subgroups (asthmatics and people with chronic urticaria). Thus, the Panel concluded that these adverse effects occur in a significant proportion of the

population and they can be serious and even life-threatening in some instances.

The Panel suggested an asthmatic response to aspirin is nonimmunologic and related to the inhibition of prostaglandin synthesis, and noted that cross-sensitivity is commonly seen with other prostaglandin synthesis inhibitors including indomethacin, flufenamic acid, mefenamic acid, ibuprofen, and phenylbutazone. The Panel suggested dermal hypersensitivity is an immunologic response, and that these individuals also appear to be susceptible to anaphylaxis and more susceptible to cross-sensitivity to salicylic acid and acetaminophen (42 FR 35346 at 35398). The Panel concluded, based on the known risk of aspirin and salicylate hypersensitivity in a significant portion of the general population, that these products should bear warnings alerting consumers who are allergic to these products to consult a doctor before using the products (42 FR 35346 at 35499). The agency has determined that a consistent approach is needed for all OTC NSAID drug products. As discussed in section IV of this document, the agency is proposing standardized allergy alert and warning statements for all OTC NSAID IAAA drug products.

In the safety discussion above (sections III.B.2.a, III.B.2.b, III.B.2.d, and III.B.3), the agency noted that the use of ibuprofen has some risk for certain individuals. GI bleeding may be increased for certain at-risk individuals (i.e., people with ulcers). For people taking anticoagulants, the risk for GI bleeding is already increased, and the use of ibuprofen by those individuals is likely to further increase that risk. Individuals with certain medical conditions are at increased risk for developing renal failure. The agency believes individuals need to be alerted to these risks. The agency is proposing that the labeling of ibuprofen include warnings related to GI bleeding, use of anticoagulant drugs, and medical conditions that predispose individuals to renal failure, using the standardized labeling format for OTC drug products.

IV. The Agency's Tentative Conclusions and Proposals

After reviewing the information submitted and other relevant information, FDA has determined that ibuprofen 200-mg tablets have been used for a material time and to a material extent to qualify for inclusion in an OTC drug monograph. Therefore, FDA is proposing that ibuprofen, in 200-mg tablet formulation, be generally recognized as safe and effective as an OTC IAAA drug for adults and children

12 years of age and older. The safety and effectiveness of ibuprofen are further supported by the data the agency evaluated in two NDAs in 1983, the findings of the AAC in 1983, and the subsequent marketing history of ibuprofen for OTC use. The agency believes ibuprofen can be marketed OTC under the monograph system for the indications previously approved under the NDA/ANDA process for adult formulations if labeled with the appropriate warnings and directions for use. The agency agrees with the petition that the proposed labeling should only include adults and children 12 years of age and older. The agency is proposing to amend the TFM for OTC IAAA drug products to include ibuprofen 200 mg, in tablet formulation, in § 343.10(g) as a safe and effective ingredient for the relief of pain and fever in adults and children 12 years of age and older, and to include specific warnings and directions for use in § 343.50(c) and (d), similar to those suggested by the petition and those approved by FDA for currently marketed OTC ibuprofen drug products under the new drug review process. The proposed labeling is in a different format than that requested by the petition. However, the format is consistent with the new OTC labeling format in § 201.66, which was issued after the petition was submitted. In addition to the warnings already included in the labeling for OTC ibuprofen drug products under the NDA/ANDA process, the agency is proposing warning statements related to GI and renal problems and use of anticoagulant drugs.

The agency also tentatively concludes that, for consistency, the "Allergy alert" and additional allergy warning statements required for ibuprofen, ketoprofen, and naproxen sodium should be extended to all OTC NSAID IAAA drug products, whether marketed under an OTC drug monograph or an NDA/ANDA. These standardized allergy alert and warning statements (in proposed § 201.324) would provide the following information:

(a) Allergy alert: [insert name of active ingredient (first letter of first word for ingredient in uppercase)] may cause a severe allergic reaction which may include: • hives • facial swelling • asthma (wheezing) • shock

(b) Do not use: • if you have ever had an allergic reaction to any other pain reliever/fever reducer [This statement appears as the first warning under the subheading "Do not use."]

(c) Stop use and ask a doctor if: • an allergic reaction occurs. Seek medical help right away. [These statements appear as the first warning under the subheading "Stop use and ask a doctor if."]

Should this proposed amendment to part 201 relating to allergy warning statements for OTC IAAA drug products be published as a final rule, then the proposed allergy warnings in §§ 343.50(c)(1)(iv)(A), (c)(1)(vi), (c)(2)(iv)(A), and (c)(2)(vi) will be replaced with a reference to the allergy warning requirements in proposed § 201.324. Final agency action on this proposal will occur in a future issue of the **Federal Register**.

V. Summary of Proposed Agency Changes

Section 201.63

1. The agency is proposing to amend the third-trimester pregnancy warning to include OTC drug products containing ibuprofen.

Section 201.324 (proposed)

2. The agency is proposing to require an "Allergy alert" and additional allergy warning statements for all OTC drug products containing NSAID IAAA active ingredients—including, but not limited to, aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen, magnesium salicylate, naproxen sodium, and sodium salicylate. (See section III of this document.)
Part 343 (21 CFR Part 343)

3. The agency is proposing to add a definition for ibuprofen in § 343.3.

4. The agency is proposing to add § 343.10(g) to include ibuprofen as an active ingredient.

5. The agency is proposing to reword the statements in § 343.20(b)(2) providing for the combination of any analgesic/antipyretic in § 343.10 and cough-cold products and in § 343.20(b)(4) providing for the combination of any analgesic in § 343.10 and diuretic drug products to provide for combinations with specific IAAA active ingredients (but not including ibuprofen). The petition did not include data for the safety and effectiveness of ibuprofen in combination with these ingredients, nor did it request ibuprofen, as a combination drug product, to be included in the TFM.

6. The agency is proposing to revise the headings in proposed § 343.50(b)(1), (c)(1)(i), and (c)(2)(i) from "For products containing any ingredient in § 343.10." to "For products containing any ingredient in § 343.10(a) through (f)" to limit those paragraphs to specific active ingredients (not including ibuprofen).

7. The agency is proposing to add § 343.50(b)(5) to include indications for ibuprofen.

8. The agency is proposing to revise the phrase related to allergy in the allergy/asthma warning for adults in proposed § 343.50(c)(1)(iv)(A) to read as follows: "Do not use this product if you

have asthma unless directed by a doctor". Similarly, for products labeled for children in § 343.50(c)(2)(iv)(A) the agency is proposing to revise the warning to read as follows: "Do not give this product to children who have asthma unless directed by a doctor".

9. The agency is proposing to revise the warning in proposed § 343.50(c)(1)(iv)(B) to reference the pregnancy/breast-feeding warnings in § 201.63(a) and (e).

10. The agency is proposing to revise the warnings in § 343.50(c)(1)(iv)(A), (c)(1)(vi), (c)(2)(iv)(A), and (c)(2)(vi) for adults and children, respectively, to require the allergy warning statements in proposed § 201.324 for products containing any ingredient in § 343.10(b) through (g). (The allergy part of the previously proposed allergy/asthma warning in § 343.50(c)(1)(iv)(A) is now covered by proposed § 201.324.)

11. The agency is proposing the following warnings for drug products containing ibuprofen in § 343.10(g) labeled for use by adults:

(a) The "Allergy alert" warnings in proposed § 201.324(a), (b), and (c).

(b) The alcohol warning in § 201.322(a)(2).

(c) The following statements after the subheading "Ask a doctor before use if you have:

- problems or serious side effects from taking pain relievers or fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach, or pain
- ulcers
- bleeding problems
- high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age".

(d) The following statements after the subheading "Ask a doctor or pharmacist before use if you are:

- under a doctor's care for a serious condition
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- taking a prescription drug for anticoagulation (blood thinning)
- taking any other drug".

(e) The following statement after the subheading "When using this product take with food or milk if stomach upset occurs":

(f) The following statements after the subheading "Stop use and ask a doctor if:

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts

• redness or swelling is present in the painful area

• any new symptoms appear".

(g) The pregnancy/breast-feeding warning in § 201.63 of this chapter.

(h) The "Keep out of reach of children" warning in § 330.1(g).

12. The agency is proposing the following directions for ibuprofen in § 343.10(g):

"• do not take more than directed [in bold type]

• adults and children 12 years and over:

• 200 milligrams³ every 4 to 6 hours while symptoms persist

• if pain or fever does not respond to 200 milligrams³, 400 milligrams³ may be used

• do not exceed 1,200 milligrams³ in 24 hours, unless directed by a doctor

• the smallest effective dose should be used

• children under 12 years: ask a doctor".

³Convert number of milligrams to proper dosage.

VI. Labeling Guidance

In the **Federal Register** of March 17, 1999 (64 FR 13254), the agency published a final rule for standardized format and content requirements for OTC drug product labeling under § 201.66. An example of some aspects of the required format for labeling of OTC IAAA drug products containing ibuprofen appears in table 3 of this document. The ibuprofen labeling in the proposed amendment to the TFM (see the codified section of this document) appears in the new format.

VII. Implementation

Ibuprofen may be marketed only under an approved drug application prior to completion of a final rule for OTC IAAA drug products.

The agency encourages manufacturers to comply voluntarily with the provisions of this proposed rule for the labeling of OTC NSAID IAAA drug products that do not contain ibuprofen and that are marketed under an OTC drug TFM prior to the completion of a final rule, despite the fact that revisions in the requirements may occur in the final rule in response to submitted comments. Such labeling may be disseminated pending issuance of a final rule, subject to the risk that the agency may, in the final rule, adopt a different position that could require relabeling, recall, or other regulatory action. Should any manufacturer choose to adopt the labeling described in this proposed rule, and should any revisions occur in the final rule, the agency will permit the use of existing stocks of

labels for those products labeled according to this proposed rule for a period of 18 months following the publication of the final rule. Those manufacturers who do not wish to revise the labeling in accordance with this proposal may continue to use the labeling proposed in the 1988 TFM (53 FR 46204 at 46258 through 46260) until a final rule becomes effective.

VIII. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the principles set out in the Executive order and in these two statutes. OMB has determined that the proposed rule is a significant regulatory action as defined by the Executive order. This economic analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation. The current inflation adjusted statutory threshold is about \$110 million.

The purpose of this proposed rule is to include ibuprofen in the monograph for OTC IAAA drug products and to require consistent "Allergy alert" and additional allergy warning statements in

the labeling of all OTC NSAID IAAA products. As most OTC NSAID IAAA products will be marketed under the final OTC IAAA monograph, these products will not have to include the allergy warnings in this proposal in product labeling until the final monograph is issued and becomes effective.

Current manufacturers of OTC 200-mg ibuprofen drug products should incur only minor one-time costs to relabel their products to meet the monograph. These costs may be offset by the elimination of the cost to maintain a market application, such as filing annual reports and submitting manufacturing supplements. Other manufacturers who may wish to market OTC 200-mg ibuprofen drug products would be able to enter the marketplace without the costs associated with obtaining an approved NDA/ANDA. Their costs would be those associated with the standard startup of any OTC drug marketed under the monograph system.

This proposed rule amends part 201 (21 CFR part 201) and will require relabeling for many OTC drug products containing NSAID IAAA ingredients. Most manufacturers that market such products under an approved NDA/ANDA already include the proposed "Allergy alert" and allergy warning statements in the product's labeling. Some manufacturers of these products, however, would have to revise the "Allergy alert" and allergy warning statements to conform to the proposed labeling. In addition, manufacturers of monograph products containing NSAID IAAA ingredients will have to relabel and include the revised allergy warnings in accord with the compliance dates specified in the IAAA products final rule. However, these allergy warnings are only one part of the overall labeling changes that will occur at that time when IAAA products are required to implement the standardized format and content requirements in § 201.66. The agency does not believe the proposed revised warnings will have a measurable impact on product usage.

The agency's analysis of impacts in the final rule that established the labeling requirements in § 201.66 applied only to products covered by the final OTC drug monographs or approved product applications (64 FR 13254 at 13283). Because these relabeling costs for OTC IAAA products have not been accounted for in earlier rules, the agency is presenting them here. The following discussion addresses the cost of product relabeling under § 201.66 that will result from the IAAA final

monograph, which includes, in part, the labeling in this proposal.

Based on information in the agency's Drug Listing System, there are approximately 102 manufacturers and 322 distributors that together account for 2,000 to 2,400 OTC NSAID IAAA products. Assuming an average of 3 individual stockkeeping units (SKUs) (individual products, packages, and sizes) per product, up to 7,200 SKUs would require the allergy warnings. Estimates of relabeling costs for the type of changes required by the IAAA final monograph vary greatly and range from \$500 to \$15,000 per SKU depending on whether the products are nationally branded or private label. Because of the large number of products affected, the agency used the same weighted average cost to relabel (i.e., \$3,600 per SKU)¹ that was used to estimate the cost of the standardized format and content requirements for OTC drug products in § 201.66 (64 FR 13254 at 13279 to 13281). Therefore, the estimated one-time cost to relabel these products is \$25.9 million (\$3,600 x 7,200 SKUs).

In addition to the above costs, some manufacturers may incur one-time and annually recurring costs if they need to increase the size of the label and/or package size of some SKUs because of the additional information required by this proposed rule. The agency had estimated that about 6,400 of the almost 100,000 marketed OTC drug SKUs may require increased label and/or package sizes to comply with the final labeling rule (64 FR 13254). As many of these 6,400 SKUs were for products subject to this final rule, much of the costs for increasing label and/or package sizes may have already been accounted for in the agency's impact analysis of that broader rule. The agency estimates that the additional lines of labeling required by this proposed rule could compel an additional 5 percent of the approximately 7,200 affected SKUs to increase their label size and/or package size.²

¹ The average weighted cost to relabel was calculated by using midpoint estimates of the cost to redesign labels and value of inventory losses of old labels by type of product and firm. The midpoint estimate for labeling design for large nationally branded SKUs is \$10,000 per SKU, the midpoint estimate for smaller branded SKUs is \$4,500 per SKU, and the cost to relabel private label SKUs is \$1,261. About 10 percent of the SKUs are nationally branded goods, 20 percent are smaller branded products, and 70 percent of the SKUs are private label goods. The average label inventory loss is about \$2,968 per SKU for nationally branded products and about \$576 per SKU for smaller branded products and private label goods. $((\$10,000 \times 0.10) + (\$4,500 \times 0.20) + (\$1,261 \times 0.70) + (\$2,968 \times 0.10) + (\$576 \times 0.90) = \$3,598)$

² FDA has assumed that all 7,200 SKUs will need to be relabeled to accommodate the standardized

Because of the large number of products affected by this rule, the agency assumes that the average cost per SKU to increase label and/or package sizes would be similar to that previously estimated by FDA for its analysis of the standardized format and content requirements for OTC drug products in § 201.66 (64 FR 13254). The model used to estimate the cost to change label/package sizes for that rule was developed by Eastern Research Group, Inc. (ERG), a private economics consulting firm under contract to FDA (Ref. 160). ERG assigned probabilities to several options for package changes, including adding a carton (if not already present), adding a fifth panel, increasing the size of the packaging or switching to a nonstandard form of labeling such as peel-back or accordion labels. Where applicable, the cost for changing a container size included container inventory loss, adjustment of the packaging line, and stability testing. Based on this model, FDA had estimated that the cost to increase label/package sizes to comply with the standardized format and content requirements for OTC drug products in § 201.66 was \$38.1 million for 6,313 SKUs, with an annual recurring cost of \$11.5 million. Consequently the average per SKU one-time cost was \$6,038, and the average per SKU recurring cost was \$1,820. Under the same assumptions, this proposed rule would impose additional one-time costs for increasing label/package sizes of \$2.2 million ($0.05 \times 7,200 \text{ SKUs} \times \$6,038$), with annual recurring costs of \$0.7 million ($0.05 \times 7,200 \text{ SKUs} \times \$1,820$). Thus, FDA estimates the overall costs of the OTC IAAA final monograph, which would include the labeling in this proposed rule, and the labeling required under § 201.66 to be \$28.1 million in one-time costs and \$0.7 million in annual recurring costs.

The proposed rule would not require any new reporting and recordkeeping activities, and no additional professional skills are needed. The March 17, 1999, standardized format and content requirements final rule for OTC drug product labeling in § 201.66 (64 FR 13254) will have an effect on the labeling of most of these products. There are no Federal rules that

duplicate, overlap, or conflict with the proposed rule.

This proposed rule should not have a significant economic impact on a substantial number of small entities. However, the agency lacks sales information for the affected companies to quantify the impact. The Small Business Administration has determined that a small firm in this industry employs fewer than 750 employees. Approximately 70 percent of the 102 manufacturers affected by this proposed rule are estimated to be small. (Note: The cost to relabel private label goods are usually borne by the manufacturer rather than the distributor.) The economic impact on any particular small firm is difficult to measure, because it will vary with the number of products affected, the number of SKUs per product, and the number of label and/or package sizes that require changing. For example, if a small manufacturer must relabel three products, or nine SKUs, the total one-time cost would be \$32,400 assuming \$3,600 as the average cost to relabel. Another small manufacturer of private label products may also need to relabel 3 products, with 3 SKUs per product, but for 20 customers. Its cost would be \$648,000. If either of these manufacturers had to increase the label and/or package sizes of their SKUs, the costs would be even higher. However, the total cost will primarily result from relabeling OTC IAAA drug products in accord with the future final monograph for those products and the standardized format and content requirements for labeling OTC drug products in § 201.66 (64 FR 13254) at the same time. The agency invites small firms to address this economic impact. (See section XI of this document—request for comments.)

Concerning the allergy alert warning, the agency considered but rejected the following alternatives: (1) Voluntary relabeling, and (2) longer implementation period. The agency does not consider either of these approaches acceptable because they do not ensure that consumers will have the most updated information needed for the safe and effective use of OTC drug products containing NSAID IAAA active ingredients. Concerning ibuprofen, the agency considered: (1) Not including ibuprofen in the monograph, and (2) marketing before a final rule is issued. The option to not include ibuprofen in the monograph was rejected because the agency considers the data presented supportive of monograph status. The agency is not allowing marketing under the monograph to occur prior to a final rule because of a number of new labeling statements being proposed. Not

allowing marketing under this proposed rule does not interrupt current OTC marketing of products containing ibuprofen and will allow the agency to consider comments on the additional labeling for OTC ibuprofen drug products before finalizing the monograph labeling. The agency does not consider an exemption for small entities who wish to market ibuprofen to be necessary because those manufacturers or distributors can enter the marketplace under the monograph at any time after a final rule issues.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC drug products that contain ibuprofen or other NSAID IAAA active ingredients. Comments regarding the impact of this rulemaking on these OTC drug products should be accompanied by appropriate documentation. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements in this proposal are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed labeling is a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

X. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposal by November 19, 2002. Submit written comments on the agency's economic impact determination by November 19, 2002. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this

format and content requirements in § 201.66 and the proposed warning. When calculating the cost of the standardized format and content requirements, FDA included the cost to increase the size of the label or the package size to accommodate the standardized format. As a result of this proposal, the warning adds additional lines of text to the label. FDA estimates that 5 percent of the 7,200 SKUs may require larger labels or package sizes to accommodate the additional text.

document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XII. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 12 months after the date of its publication in the **Federal Register** or at a later date if stated in the final rule. The compliance date for products with annual sales less than \$25,000 would be 24 months after the date of publication of a final rule in the **Federal Register** or at a later date if stated in the final rule.

XIII. References

The following references are on display in the Dockets Management Branch (address above), under Docket No. 77N-0941 (or 77N-0094, where indicated), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. CP13, Docket No. 77N-0094, Dockets Management Branch.
2. Comment No. C233, Docket No. 77N-0094, Dockets Management Branch.
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5. Minutes of the Seventeenth Meeting of the Arthritis Advisory Committee, OTC Vol. 03BTFM(I), Docket No. 77N-0941, Dockets Management Branch.
6. Summary Basis of Approval for New Drug Application for Ibuprofen (200 mg), OTC Vol. 03BTFM(I), Docket No. 77N-0941, Dockets Management Branch.
7. Comment No. CP3, Docket No. 77N-0094, Dockets Management Branch.
8. Comment No. PDN002, Docket No. 77N-0094, Dockets Management Branch.
9. Memoranda of Telecon Between Representatives of Whitehall Robins Health Care and FDA on August 6, 1998, and August 26, 1998, coded MT12 and MT13, respectively, Docket No. 77N-0094, Dockets Management Branch.
10. Comment No. SUP44, Docket No. 77N-0094, Dockets Management Branch.
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List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 343

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 201 and 343 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.63 is amended by revising paragraph (e) to read as follows:

§ 201.63 Pregnancy/breast-feeding warning.

* * * * *

(e) The labeling of orally or rectally administered OTC aspirin- and ibuprofen-containing products must bear a warning that immediately follows the general warning identified in paragraph (a) of this section. The warning shall be as follows:

"It is especially important not to use" [select "aspirin," "carbaspirin calcium," or "ibuprofen," as appropriate] "during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery."

3. Section 201.324 is added to subpart G to read as follows:

§ 201.324 Over-the-counter drug products containing internal analgesic/antipyretic active ingredients; required allergy warning statements.

The labeling for all over-the-counter (OTC) drug products containing nonsteroidal anti-inflammatory internal analgesic/antipyretic active ingredients—including but not limited to aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen, magnesium salicylate, naproxen sodium, and sodium salicylate—whether subject to an applicable OTC drug monograph or an approved drug application, contains the following allergy warnings under the heading "Warnings":

(a) "Allergy alert: [insert name of active ingredient (first letter of first word for ingredient in uppercase)] may cause a severe allergic reaction which may include: [bullet]¹ hives [bullet] facial swelling [bullet] asthma (wheezing) [bullet] shock".

(b) "Do not use [insert bullet if more than one warning occurs under this subheading] if you have ever had" or for products labeled only for use in children under 12 years of age, "Do not use [insert bullet if more than one warning occurs under this subheading] if your child has ever had" followed by, "an allergic reaction to any other pain reliever/fever reducer". [This statement appears as the first warning under the subheading "Do not use."]

(c) "Stop use and ask a doctor if [insert bullet if more than one warning occurs under this heading] an allergic reaction occurs. Seek medical help right away." [These statements appear as the first warning under the subheading "Stop use and ask a doctor if."]

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

PART 343—INTERNAL ANALGESIC, ANTIPYRETIC, AND ANTIRHEUMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

4. The authority citation for 21 CFR part 343 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

5. Section 343.3 is amended by alphabetically adding a definition for ibuprofen to read as follows:

§ 343.3 Definitions.

* * * * *

Ibuprofen. A racemic mixture of the S-[+] and R-[-] enantiomers of ibuprofen in a tablet formulation for adults and children 12 years and older.

* * * * *

6. Section 343.10, as proposed at 53 FR 46255, November 16, 1988, is further amended by adding paragraph (g) to read as follows:

§ 343.10 Analgesic-antipyretic active ingredients.

* * * * *

(g) Ibuprofen 200-milligram tablet.

* * * * *

7. Section 343.20, as proposed at 53 FR 46255, November 16, 1988, is further amended by revising paragraphs (b)(2) and (b)(4) to read as follows:

§ 343.20 Permitted combinations of active ingredients.

* * * * *

(b) * * *

(2) *Analgesic-antipyretic active ingredients identified in § 343.10(a) through (f) and cough-cold combinations.* See § 341.40 of this chapter.

* * * * *

(4) *Analgesic and diuretic combinations.* Any analgesic identified in § 343.10(a) through (f) or any combination of analgesics identified in § 343.20(a) may be combined with any diuretic identified in § 357.1012 of this chapter provided the product bears labeling indications in accordance with § 357.1060(b) of this chapter.

8. Section 343.50, as proposed at 53 FR 46255, November 16, 1988, is further amended by revising the headings in paragraphs (b)(1), (c)(1)(i), and (c)(2)(i); and the text of paragraphs (c)(1)(iv)(A), (c)(1)(iv)(B), (c)(1)(vi), (c)(2)(iv)(A), and (c)(2)(vi); and by adding paragraphs (b)(5), (c)(1)(ix), and (d)(7) to read as follows:

§ 343.50 Labeling of analgesic-antipyretic drug products.

* * * * *

(b) * * *

(1) *For products containing any ingredient identified in § 343.10(a) through (f).* * * *

(5) *For products containing ibuprofen identified in § 343.10(g).* The labeling of the product contains any of the indications in § 343.50(b) except "sore throat."

(c) * * *

(1) * * *

(i) *For products containing any ingredient identified in § 343.10(a) through (f).* * * *

* * * * *

(iv) * * *

(A) "Do not use this product if you have asthma unless directed by a doctor".

(B) The labeling contains the pregnancy/breast-feeding warnings set forth in § 201.63(a) and (e) of this chapter.

* * * * *

(vi) *For products containing any ingredient identified in § 343.10(b) through (g).* The labeling of the product contains the allergy warnings set forth in § 201.324(a), (b), and (c) of this chapter.

* * * * *

(ix) *For products containing ibuprofen identified in § 343.10(g).* (A) The alcohol warning set forth in § 201.322(a)(2) of this chapter appears after the subheading "Alcohol warning:."

(B) "Ask a doctor before use if you have: [bullet]¹ problems or serious side effects from taking pain relievers or fever reducers [bullet] stomach problems that last or come back, such as heartburn, upset stomach, or pain [bullet] ulcers [bullet] bleeding problems [bullet] high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age".

(C) "Ask a doctor or pharmacist before use if you are: [bullet] under a doctor's care for any serious condition [bullet] taking any other product that contains ibuprofen, or any other pain reliever/fever reducer [bullet] taking a prescription drug for anticoagulation (blood thinning) [bullet] taking any other drug".

(D) "When using this product: [insert bullet if more than one warning occurs under this subheading] take with food or milk if stomach upset occurs".

(E) In addition to the warning required in § 201.324(c) of this chapter, the following statements appear after the subheading "Stop use and ask a doctor if: [bullet] pain gets worse or

lasts more than 10 days [bullet] fever gets worse or lasts more than 3 days [bullet] stomach pain gets worse or lasts [bullet] redness or swelling is present in the painful area [bullet] any new symptoms appear".

(F) The labeling contains the pregnancy/breast-feeding warnings set forth in § 201.63(a) and (e) of this chapter.

(2) * * *

(i) *For products containing any ingredient identified in § 343.10(a) through (f).* * * *

* * * * *

(iv) * * *

(A) "Do not give this product to children who have asthma unless directed by a doctor".

* * * * *

(vi) *For products containing any ingredient in § 343.10(b) through (g).* The labeling contains the allergy warnings set forth in § 201.324(a), (b), and (c) of this chapter.

* * * * *

(d) * * *

* * * * *

(7) *For products containing ibuprofen identified in § 343.10(g).* The labeling states "[bullet]¹ do not take more than directed [in bold type] [bullet] adults and children 12 years and over: [bullet] 200 milligrams² every 4 to 6 hours while symptoms persist [bullet] if pain or fever does not respond to 200 milligrams², 400 milligrams² may be used [bullet] do not exceed 1,200 milligrams² in 24 hours, unless directed by a doctor [bullet] the smallest effective dose should be used [bullet] children under 12 years: ask a doctor".

* * * * *

Dated: January 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AL-200234; FRL-7264-4]

Proposed Determination of Attainment of 1-hour Ozone Standard as of November 15, 1993, for the Birmingham, AL, Marginal Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to determine that the Birmingham marginal ozone nonattainment area (hereinafter referred to as the Birmingham area) attained the 1-hour ozone National Ambient Air Quality Standard (NAAQS) by November 15, 1993, the date required by the Clean Air Act (CAA). The Birmingham area is comprised of Jefferson and Shelby Counties. On July, 10, 2002, the United States District Court for the District of Columbia concluded that EPA failed to exercise its non-discretionary duty to make a final attainment determination for the Birmingham area by May 15, 1994. The Court required that EPA make a formal attainment determination within 120 days from date of opinion. *Sierra Club v. Whitman*, No. 00-2206 (D.D.C. July 10, 2002). Therefore, in response to the Court's order, EPA proposes to determine that the Birmingham area attained the 1-hour ozone standard by its statutory attainment date of November 15, 1993.

DATES: Written comments must be received on or before September 20, 2002.

ADDRESSES: All comments should be addressed to: Sean Lakeman; Regulatory Development Section; Air Planning Branch; Air, Pesticides and Toxics Management Division; U.S. Environmental Protection Agency Region 4; 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960.

Copies of documents relative to this action are available at the following address for inspection during normal business hours: Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960.

The interested persons wanting to examine these documents should make an appointment at least 24 hours before the visiting day and reference file AL-200234.

FOR FURTHER INFORMATION CONTACT: Sean Lakeman, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960. The telephone number is (404) 562-9043. Mr. Lakeman can also be reached via electronic mail at lakeman.sean@epa.gov.

SUPPLEMENTARY INFORMATION:

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- I. What Action Is EPA Proposing To Take?
- II. What Is the Background for This Action?
- III. Why Is EPA Taking This Action?

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

² Convert number of milligrams to proper dosage.

IV. Proposed Action
V. Administrative Requirements.

I. What Action Is EPA Proposing To Take?

Pursuant to section 181(b)(2)(A) of the CAA, EPA is proposing to determine that the Birmingham area has attained the 1-hour NAAQS for ozone by November 15, 1993, the date required by section 181(a)(1) of the CAA. This determination is based upon three years of complete, quality-assured, ambient air monitoring data for the years 1991–1993 which indicate that Birmingham area attained the 1-hour ozone NAAQS.

II. What Is the Background for This Action?

The Clean Air Act (CAA) requires EPA to establish NAAQS for certain pollutants that cause or contribute to air pollution that is reasonably anticipated to endanger public health or welfare (CAA sections 108 and 109). In 1979, EPA promulgated the 1-hour 0.12 parts per million (ppm) ground-level ozone NAAQS (44 FR 8202 (February 8, 1979)). Ground-level ozone is not emitted directly by sources. Rather, emissions of nitrogen oxides (NO_x) and volatile organic compounds (VOC) react in the presence of sunlight to form ground-level ozone. NO_x and VOC are referred to as precursors of ozone.

An area exceeds the 1-hour ozone NAAQS each time an ambient air quality monitor records a 1-hour average ozone concentration above 0.124 ppm. An area is violating the NAAQS when the average of expected exceedances during a consecutive three-year period is greater than 1 at any one monitor (40 CFR part 50, appendix H). The CAA required EPA to designate as nonattainment any area that was violating the 1-hour ozone NAAQS, generally based on air quality monitoring data from the three-year period from 1987–1989, or any area

contributing to a violation (CAA section 107(d)(4); 56 FR 56694 (November 6, 1991)). The CAA further classified these areas, based on the area's design value (*i.e.*, the 4th highest ozone value during the relevant three year period at the violating monitor with the highest ozone levels), as marginal, moderate, serious, severe or extreme (CAA section 181(a)). Marginal areas were suffering the least significant air pollution problems.

The control requirements and dates by which attainment needs to be achieved vary with the area's classification. Marginal areas were subject to the fewest mandated control requirements and had the earliest attainment date. Marginal areas were required to attain the 1-hour NAAQS by November 15, 1993. Section 181(a) of the CAA.

The Birmingham area was originally designated as a 1-hour ozone nonattainment area by EPA on March 3, 1978 (43 FR 8962). The Birmingham nonattainment area at that time was geographically defined as Jefferson County, Alabama. On November 6, 1991, by operation of law under section 181(a) of the CAA, EPA classified the Birmingham nonattainment area as a marginal nonattainment area for ozone and added Shelby County to the nonattainment area (56 FR 56693). The nonattainment classification for the Birmingham marginal ozone area was based on ambient air sampling measurements for ozone made during 1987–1989. The area was required to attain the 1-hour ozone NAAQS by November 15, 1993, (*i.e.*, three years from the enactment of the CAA) which is the date set forth in section 181(a)(1).

For further background, see the Court's opinion in *Sierra Club v. Whitman*, No. 00–2206 (D.D.C. July 10, 2002).

Section 181(b)(2)(A) of the Clean Air Act states that:

Within 6 months following the applicable attainment date (including any extension thereof) for an ozone nonattainment area, the Administrator shall determine, based on the area's design value (as of the attainment date), whether the area attained the standard by that date. Except for any Severe or Extreme area, any area that the Administrator finds has not attained the standard by that date shall be reclassified by operation of law in accordance with table 1 of subsection (a) to the higher of—

(i) the next higher classification for the area, or

(ii) the classification applicable to the area's design value as determined at the time of the notice required under subparagraph (B).

No area shall be reclassified as extreme under clause (ii).

After the end of the 1993 ozone season, the Birmingham area had three years of quality assured air monitoring data (1991, 1992 and 1993) which demonstrated that the 1-hour ozone NAAQS was attained. Table 1 shows the number of exceedances at each of the monitoring sites in Jefferson and Shelby Counties. No individual monitor recorded more than two exceedances during the three year period. The national 1-hour primary and secondary ambient air quality standard for ozone is attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than 1, averaged over a three year period (40 CFR part 50, appendix H). The design value for the Birmingham area is 0.124 ppm, based on the fourth highest 1-hour value recorded at the Bearden Farm monitor. The recorded values for that monitor were 0.144, 0.125, 0.124, and 0.124 ppm.

TABLE 1.—BIRMINGHAM AREA 1-HOUR OZONE NAAQS EXCEEDANCES FROM 1991 TO 1993

Year	Jefferson County					Shelby County
	Fairfield	Route 8 McAdory	Tamassee LA	Pinson High Sch	Tarrant Elem Sch	Bearden Farm
1991	0	0	0	0	0	0
1992	0	0	0	1	1	0
1993	0	0	1	0	0	2

Therefore, in accordance with section 181(b)(2) of the CAA, EPA proposes to determine that the Birmingham area attained the standard by the area's November 15, 1993, attainment date.

III. Why Is EPA Taking This Action?

In 2000, the Sierra Club brought suit in district court, seeking, among other claims, an order requiring EPA to issue a determination pursuant to section

181(b) as to whether the Birmingham area had attained the NAAQS.

On July, 10, 2002, the United States District Court for the District of Columbia concluded that EPA failed to perform its non-discretionary duty to

make a final attainment determination for the Birmingham area (CAA section 181(6)) by May 15, 1994. The Court required EPA to make a formal determination within 120 days from the date of its opinion. *Sierra Club v. Whitman*, No. 00–2206 (D.D.C. July 10, 2002). In compliance with the Court's order, EPA proposes to determine that the Birmingham area had attained the 1-hour ozone standard by November 15, 1993.

IV. Proposed Action

Pursuant to section 181(b)(2)(A) of the CAA, EPA is proposing to determine that the Birmingham area attained the 1-hour NAAQS for ozone by November 15, 1993. This determination is based upon the area's design value as of its attainment date, and upon three years of complete, quality-assured, ambient air monitoring data for the years 1991–1993 which indicate that Birmingham area attained the 1-hour ozone NAAQS.

V. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have

substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed determination of attainment does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 9, 2002.

J. I. Palmer, Jr.,

Regional Administrator, Region 4.

[FR Doc. 02–21286 Filed 8–20–02; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[I.D. 080702E]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits (EFPs)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of a proposal for EFPs to conduct experimental fishing; request for comments.

SUMMARY: NMFS announces that the Administrator, Northeast Region, NMFS (Regional Administrator), has determined that an application for EFPs contains all of the required information and warrants further consideration. The Regional Administrator is considering the impacts of the activities to be authorized under the EFPs with respect to the Northeast (NE) Multispecies Fishery Management Plan (FMP). However, further review and consultation may be necessary before a final determination is made to issue EFPs. Therefore, NMFS announces that the Regional Administrator proposes to issue EFPs in response to an application submitted by the Groundfish Group Associated Fisheries of Maine (Associated Fisheries of Maine), in collaboration with Manomet Center for Conservation Sciences (Manomet). These EFPs would allow up to 12 vessels to fish for yellowtail flounder in NE multispecies year-round Closed Area II (CA II) during the months of August through December, 2002, and July, 2003, with the potential of the August trips occurring in 2003 depending on when the EFPs are issued.

The purpose of the study is to collect observer-based data to determine whether seasonal access to portions of CA II for the purpose of harvesting Georges Bank (GB) yellowtail flounder is possible without significant bycatch and discard of other regulated NE multispecies, particularly Atlantic cod and haddock. This information could then be used by the New England Fishery Management Council (Council) and NMFS to determine the feasibility of establishing a seasonal access program that would allow the harvest of GB yellowtail flounder in portions of CA II.

DATES: Comments on this action must be received at the appropriate address or

fax number (see **ADDRESSES**) on or before September 5, 2002.

ADDRESSES: Written comments should be sent to Patricia A. Kurkul, Regional Administrator, National Marine Fisheries Service, Northeast Regional Office, 1 Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on Yellowtail EFP Proposal." Comments may also be sent via facsimile (fax) to (978) 281-9135. Comments will not be accepted if submitted via e-mail or the Internet.

Copies of the Environmental Assessment (EA) are available from the NE Regional Office at the same address.

FOR FURTHER INFORMATION CONTACT: Allison Ferreira, Fishery Policy Analyst, (978) 281-9103, email allison.ferreira@noaa.gov

SUPPLEMENTARY INFORMATION:

Background

Three year-round closed areas were established in 1994 under Amendment 5 to the FMP to provide protection to concentrations of regulated NE multispecies, particularly Atlantic cod, haddock, and yellowtail flounder. These closure areas, Closed Area I, Closed Area II and the Nantucket Lightship Closure Area, have proven to be effective in improving the stock status of several species, in particular, the status of GB yellowtail flounder. Spawning stock biomass (SSB) for GB yellowtail flounder increased from 2,600 mt in 1992 to 33,500 mt in 1999. Mean stock biomass also increased from 4,500 mt in 1992 to 49,600 mt in 1999. In 2001, the Transboundary Resources Assessment Committee's (TRAC) Advisory Report on Stock Status estimated GB yellowtail flounder SSB to be between 37,000 and 50,500 mt (80-percent probability) and the mean biomass to be between 48,000 and 66,500 mt (80-percent probability). Furthermore, in 2001, the Multispecies Monitoring Committee (MMC) estimated the mean biomass for GB yellowtail flounder to be 55,437 mt, which is well above the biomass target (B_{target}) of 49,000 mt. In addition, the MMC estimated the 2001 fishing mortality rate (F) for GB yellowtail flounder to be $F_{2001}=0.14$, which is well below the target F of $F_{0.1}=0.25$.

In their EFP application, Manomet and the Associated Fisheries of Maine state that common knowledge within the fishing and scientific communities suggests that Atlantic cod and haddock are less available in certain portions of CA II during specific seasons. The applicants feel that there is a need to support this knowledge with scientific data, potentially enabling the rebuilt GB yellowtail flounder resource to be

utilized without impacting the management programs that currently protect the rebuilding stocks of cod and haddock on Georges Bank.

Proposed EFP

The Associated Fisheries of Maine, in collaboration with Manomet, have submitted an application for 17 EFPs (12 vessels and 5 alternates) that would exempt these vessels from the days-at-sea (DAS) requirements specified under 50 CFR 648.80 and 648.82, and CA II restrictions specified under § 648.81. The proposed study would occur in the area south of 41°30' N. lat. within CA II. The experiment would consist of two vessels conducting one concurrent 5-day trip each month for the months of August through December, 2002 and July, 2003, for a total of 6 concurrent trips and 12 total vessel trips for the study. Each trip would consist of 2 transiting days and 3 sampling days, for a total of 24 vessel transiting days and 36 vessel sampling days over the course of the study. Participating vessels would be prohibited from fishing in areas outside of CA II during an experimental fishing trip. In order to offset the cost of the experiment, the applicant has requested that the participating vessels be exempt from DAS requirements while participating in the proposed experimental fishery.

Survey operations would follow a pre-determined sampling design. The sample area would be divided into grids of approximately 6 square miles (15.5 sq. km) During each trip, hauls would be conducted in each grid, with each haul lasting 20 minutes. The sampling design would enable comparison trawls between vessels in order to standardize catch data between vessels. A total of 51 hauls, 26 hauls for vessel 1 and 25 hauls for vessel 2, would be conducted during each trip. Vessels would utilize standard otter trawl gear having a codend mesh size of 6.5-inch (16.5 cm) square mesh, the minimum mesh size for the GB Regulated Mesh Area.

A total allowable catch (TAC) of GB yellowtail flounder of 220 mt would be established for the experimental fishery. This equates to approximately 40,000 lb (18,144 kg) of yellowtail flounder per vessel, per trip. Incidental catch of cod and haddock would be limited to 2,000 lb (907 kg) and 3,000 lb (1,361 kg) per DAS, respectively. In addition, all fish landed would have to meet minimum size requirements.

Several species of skates are found in the southern portion of CA II where the proposed experimental fishery would be conducted. Due to concerns over skate bycatch, particularly the bycatch of thorny and barndoor skate, the

applicants have agreed to identify and record all skates caught and return all skates caught to the sea immediately in order to minimize mortality. No skates would be retained for landing or sale. In addition, the applicants have stated that the bycatch of skates would be avoided to the extent practicable.

A minimum of two observers, consisting of Manomet scientific staff, would be present on board each participating vessel, equating to 100-percent observer coverage for this experimental fishery. All catch would be sorted, weighed and recorded by species. In addition, commercially important species, including all skate species, would be individually weighed and measured. Observers would be responsible for collecting all biological and environmental data on NMFS observer forms. Interim reports would be provided to NMFS at the end of each trip outlining total catch, including bycatch and discards. Participating vessels may also be required to report estimates of daily catch to NMFS via a call-in system in order to monitor the GB yellowtail TAC of 220 mt requested for this experimental fishery.

The EFPs would contain a provision that the Regional Administrator has the authority to reconsider the continuation of the proposed experimental fishery on a month-by-month basis. The Regional Administrator would be authorized to terminate the experimental fishery if the yellowtail flounder TAC of 220 mt is exceeded or if excessive bycatch of cod, haddock and other species of concern (including, but not limited to, skate) occurs during any given trip.

A draft EA has been prepared that analyzes the impacts of the proposed experimental fishery on the human environment. This draft EA concludes that the proposed activities to be conducted under the requested EFPs are consistent with the goals and objectives of the FMP, would not be detrimental to the well-being of any stocks of fish harvested, and would have no significant environmental impacts. The draft EA also concludes that the proposed experimental fishery would not be detrimental to Essential Fish Habitat, marine mammals, or protected species.

EFPs would be issued to up to 17 vessels exempting them from the DAS requirements and CA II restrictions of the FMP.

Based on the results of the proposed experimental fishery, this action may lead to future rulemaking.

Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested

parties the opportunity to comment on applications for proposed EFPs.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 14, 2002.

Virginia M. Fay,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 02-21316 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

Notices

Federal Register

Vol. 67, No. 162

Wednesday, August 21, 2002

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 01-018-3]

Availability of Evaluation Related to FMD Status of Great Britain; Correction

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments; correction.

SUMMARY: In a notice published in the **Federal Register** on July 16, 2002 (Docket No. 01-018-2), we announced the availability for review and comment of a document that assesses the foot-and-mouth disease status of Great Britain (England, Scotland, Wales, and the Isle of Man) and the related disease risks associated with importing animals and animal products into the United States from Great Britain. The notice contained an incorrect Internet address. This document corrects that error.

DATES: We will consider all comments that we receive on Docket No. 01-018-2 on or before September 16, 2002.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 01-018-2, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 01-018-2. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 01-018-2" on the subject line.

You may read the evaluation and any comments that we receive on the

evaluation in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Anne Goodman, Supervisory Staff Officer, Regionalization Evaluation Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

SUPPLEMENTARY INFORMATION: On July 16, 2002, we published in the **Federal Register** (67 FR 46628-46629, Docket No. 01-018-2) a notice of availability and request for comments for a document entitled "APHIS Evaluation of FMD Status of Great Britain (England, Scotland, Wales, and the Isle of Man)" (May 2002). This evaluation assesses the foot-and-mouth disease status of Great Britain and related disease risks associated with importing animals and animal products into the United States from Great Britain. This evaluation will serve as a basis to determine whether to relieve certain prohibitions and restrictions on the importation of ruminants and swine and fresh (chilled or frozen) meat and other products of ruminants and swine into the United States from Great Britain. We are making the evaluation available for public comment for 60 days. Comments must be received on or before September 16, 2002.

In the background portion of the notice, we provided an Internet address where the evaluation could be viewed. This address was incorrect. The Internet address should have read: <http://www.aphis.usda.gov/vs/reg-request.html>. This document corrects that error.

Correction

In FR Doc. 02-17795, published on July 16, 2002 (67 FR 46628-46629), make the following correction: On page

46629, first column, fourth full paragraph, in the first sentence, correct "http://www.aphis.usda.gov/vs/reg-request.html" to read "http://www.aphis.usda.gov/vs/reg-request.html".

Done in Washington, DC, this 15th day of August, 2002.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 02-21275 Filed 8-20-02; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Forest Service

Dixie National Forest, Utah, Long Deer Vegetation Management Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare a Supplemental Environment Impact Statement.

SUMMARY: The USDA Forest Service will prepare a Supplemental Environmental Impact Statement (SEIS) to the South Spruce Ecosystem Rehabilitation Project EIS (1999) to implement vegetation management treatments in the spruce/fir forests within the Cedar City Ranger District, Dixie National Forest, Utah. The agency gives notice of the full environmental analysis and decision-making process that will occur on the proposal so that interested and affected people may become aware of how they can participate in the process and contribute to the final decision.

DATES: Comments concerning the scope of the analysis must be received by thirty days after publication of this Notice of Intent in the **Federal Register**. The draft supplemental environmental impact statement is expected in September 2002. The final supplemental environmental impact statement is expected in December 2002.

ADDRESSES: Send written comments to: Long Deer Interdisciplinary Team Leader, Cedar City Ranger District, Dixie National Forest, 1789 Wedgewood, Cedar City, Utah 84720.

FOR FURTHER INFORMATION CONTACT:

Long Deer Interdisciplinary Team Leader, Cedar City Ranger District, Dixie National Forest, 1789 Wedgewood, Cedar City, Utah 84720.

SUPPLEMENTARY INFORMATION: The proposed project is located in a 10,436 acre analysis area in portions of the Tommy, Duck, and Upper Midway Creek watersheds. Approximately 7,514 acres of the project area are forested and 2,922 acres are non-forested. The proposed commercial conifer treatment areas currently are infested with spruce beetle (*Dendroctonus rufipennis*).

The purpose of the project is to harvest approximately 2,443 acres of dead, dying, and high risk Engelmann spruce trees to recover wood products that would otherwise be lost, while still meeting desired resources objectives for the project area. Minor amounts of subalpine fir trees (less than 15% of the total removed) would also be removed to encourage open growth, spruce or subalpine fir regeneration, improve residual stand vigor, or that will likely be damaged or killed during the removal of the spruce trees.

Rehabilitation of areas heavily impacted by bark beetle mortality through the completion of natural and artificial regeneration activities would occur as needed. An estimated 1,000 acres would be planted with spruce seedlings. Reforestation is essential to providing for the most rapid progression toward the desired future condition for forest cover in the project area.

Aspen regeneration of approximately 470 acres is also included in this proposal. These areas are included with the 2,443 acres of salvage/improvement treatments. Treatments would include tree removal followed by burning or mechanical treatment (commercial harvest) with or without burning.

Within the areas proposed for treatments, approximately 102 acres would be machine piled and burned and 619 acres would be broadcast burned to reduce fuels to the desired levels and to help stimulate the regeneration of aspen.

Travel management is proposed for portions of the project area. The purpose of this activity is to restore and rehabilitate ecological values in areas where excessive numbers of open roads exist; primarily to offset the loss of big game hiding cover from harvest activities. Moving these portions of the project area toward or below the Land Resource Management Plan guideline of two miles of open road per square mile will reduce the adverse environmental impacts associated with excessive numbers of open roads and loss of cover. A reduction in open road density will also reduce long-term maintenance costs while promoting safe, efficient public travel on the open road system. Road closures would be accomplished with earth and rock barriers, fences, or

gates. The open road density for the analysis area would be reduced from the current 2.39 miles per square mile to 1.70 miles per square mile.

Vegetation management treatments involving commercial harvest, aspen regeneration, and travel management would occur on National Forest system lands located within portions of section 19, 30–32 of Township (T) 37 South (S), Range (R) 8 West (W); sections 13, 14, 23–26, 35, and 36 of T37S, R8½W; sections 11–14, 23–26, 35 and 36 of T37S, R9W; sections 1 and 2 of T38S, R9W; and sections 4–6, and 8–10 of T38S, R8W, Salt Lake City Meridian, Iron and Kane Counties, UT.

The transportation system required to access commercial harvest areas is in place. All skid trails would be obliterated and may be seeded upon completion of the project.

The proposed actions would implement management direction, contribute to meeting the goals and objectives identified in the DNF–LRMP, and move the project area toward the desired condition. This project SEIS would be tiered to the Dixie National Forest LRMP EIS (1986), which provides goals, objectives, standards and guidelines for the various activities and land allocations on the Forest.

The Forest Service would analyze and document direct, indirect, and cumulative environmental effects for a range of alternatives. Each alternative would include mitigation measures and monitoring requirements. One alternative to the proposed action has been identified at this time. Alternative A was developed to address an issue identified during scoping. This alternative would close less roads in order to maintain access to dispersed campsites and popular off highway vehicle routes. The open road density would be reduced from the existing 2.39 miles per square mile to 1.80 miles per square mile under this alternative. All other actions would be identical to the Proposed Action. No other issue has been identified beyond those initially identified and analyzed under separate alternatives in the South Spruce Ecosystem Rehabilitation Project EIS.

Responsible Official: Randy Swick, Acting Forest Supervisor, Dixie National Forest, is the responsible official. He can be reached by mail at 1789 Wedgewood, Cedar City, Utah, 84720.

Comments Requested: Comments will continue to be received and considered throughout the analysis process. Comments received in response to this notice and through scoping, including names and addresses of those who comment, will be considered part of the public record of this proposed action

and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision under 36 CFR parts 215 or 217. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under the FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within a specified number of days.

Early Notice of Importance of Public Participation in Subsequent Environmental Review: A draft environmental impact statement will be prepared for comment. The draft SEIS is expected to be filed with the EPA (Environmental Protection Agency) and to be available for public review. At that time the EPA will publish a notice of availability of the draft SEIS in the **Federal Register**. The comment period for the draft environmental impact statement will be forty-five days from the date the EPA's notice of availability appears in the **Federal Register**. Comments on the draft SEIS should be as specific as possible and may address the adequacy of the statement or the merits of the alternatives discussed (Reviewers may wish to refer to the *Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act* at 40 CFR 1503.3 in addressing these points).

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewers' position and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could have been raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental

impact statement may be waived or dismissed by the courts. *City of Angoon v. Hodel*, (9th Circuit, 1986) and *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at the time it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns about the proposed action, comments on the draft supplemental environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

In the final SEIS, the Forest Service is required to respond to substantive comments and responses received during the comment period that pertain to the environmental consequences discussed in the draft SEIS and applicable laws, regulations, and policies considered in making a decision regarding the proposal. The Responsible Official will document the decision and rationale for the decision in a Record of Decision. The final SEIS is scheduled for completion in December, 2002. The decision will be subject to review under Forest Service Appeal Regulations.

Dated: August 9, 2002.

Randall G. Swick,

Acting Forest Supervisor, Dixie National Forest.

[FR Doc. 02-21215 Filed 8-20-02; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Revision of the Land and Resource Management Plan for the Medicine Bow National Forest, Albany County, Carbon County, Converse County, Natrona County, Platte County, WY

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to prepare an environmental impact

statement in conjunction with revision of the Land and Resource Management Plan for the Medicine Bow National Forest.

SUMMARY: The Forest Service will prepare an environmental impact statement in conjunction with the revision of the Land and Resource Management Plan (hereafter referred to as the Forest Plan or Plan) for the Medicine Bow National Forest.

DATES: Comments concerning the issues, concerns and scope of the analysis with regard to the proposed action were requested to be received in writing by November 15, 1999. The Forest Service expects to file a Draft Environmental Impact Statement with the Environmental Protection Agency (EPA) and make it available for public comment in December 2002. The agency expects to file the Final Environmental Impact Statement in December 2003.

ADDRESSES: Send written comments to: Mary Peterson, Forest Supervisor, Medicine Bow-Routt National Forests, 2468 Jackson Street, Laramie, Wyoming 82070.

FOR FURTHER INFORMATION CONTACT: Dave Harris, Planning Team Leader, (307) 745-2403.

Responsible Official: Rick D. Cables, Rocky Mountain Regional Forester at P.O. Box 25127, Lakewood, CO 80225-0127.

Cooperating Agencies: State of Wyoming, through the Office of Federal Land Policy; Bureau of Land Management; and Conservation Districts.

SUPPLEMENTARY INFORMATION: This is a revised Notice of Intent for the prior notice promulgated in the **Federal Register**, Vol. 64, No. 194, on October 7, 1999 page 54609. The Notice of Intent is being revised for the following reasons:

(1) The draft EIS has been delayed two years. The original expected release date was October 2000; the new expected date is December 2002. The final EIS is expected to be published December 2003.

(2) Two cooperating agencies have been added. The Bureau of Land Management in Wyoming (USDI-BLM) will cooperate on the preparation of the EIS and decisions regarding mineral leasing. Seven Wyoming Conservation Districts (Little Snake River, Saratoga-Encampment-Rawlins, Medicine Bow, Conserve County, Laramie County, and Laramie Rivers Conservation Districts and the Platte County Resource District, hereinafter referred to as County Conservation Districts) will cooperate in water quality monitoring, planning for

impaired watersheds, socio-economic analysis, and public involvement.

(3) The responsible official has changed. Rick D. Cables is the current Regional Forester for the Rocky Mountain Region and responsible official for the Medicine Bow Forest Plan Revision.

Pursuant to part 36 Code of Federal Regulations (CFR) 219.10(g), the Regional Forester for the Rocky Mountain Region gives notice of the agency's intent to prepare an environmental impact statement for the revision effort described above. According to 36 CFR 219.10(g), land and resource management plans are ordinarily revised on a 10- to 15-year cycle. The existing Forest Plan was approved November 20, 1985.

The Forest Service is the lead agency in this revision effort. The State of Wyoming, by and through the Office of Federal Land Policy; USDI-BLM; and County Conservation Districts are cooperating agencies by virtue of special expertise and jurisdiction. The State of Wyoming was listed as a cooperating agency in the 1999 Notice of Intent.

Forest Plans describe the intended management of National Forests. Agency decisions in the Plan will do the following:

- * Establish multiple-use goals and objectives (36 CFR 219.11);
- * Establish forestwide management requirements (standards and guidelines) to fulfill the requirements of 16 USC 1604 applying to future activities (resource integration requirements, 36 CFR 219.13 to 219.27);
- * Establish management areas and management area direction (management area prescriptions) applying to future activities in that management area (resource integration and minimum specific management requirements) 36 CFR 219.11(c);
- * Establish monitoring and evaluation requirements (36 CFR 219.11(d));
- * Determine suitability and potential capability of lands for producing forage for grazing animals and for providing habitat for management indicator species (36 CFR 219.20), designate lands not suited for timber production, and, where applicable, establish allowable timber sale quantity (36 CFR 219.14, 219.15, and 219.21);
- * Where applicable to oil and gas resources, determine the planning area leasing decision (lands administratively available for leasing) and the leasing decision for specific lands [36 CFR 228.102(4)(d) & (e)]. Where applicable, BLM will issue a decision document on leasing for federal minerals, both under

Forest Service administered surface and under private surface.

* Where applicable, recommend Wild and Scenic River designations, in cooperation with the National Park Service, in accordance with 16 USC 1274; and

* Where applicable, recommend non-Wilderness allocations or Wilderness recommendations for roadless areas (26 CFR 219.17).

The authorization of project level activities within the planning area occurs through project decision-making, the second stage of forest and grassland planning. Project-level decisions must comply with National Environmental Policy Act (NEPA) procedures and must include a determination that the project is consistent with the Management Plan, or the Plan must be amended according to the National Forest Management Act (NFMA).

Release and Review of the EIS: The DEIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public comment by December 2002. At that time, the EPA will publish a notice of availability for the DEIS in the **Federal Register**. The comment period on the DEIS will be 90 days from the date the EPA publishes the notice of availability in the **Federal Register**.

Reviewers of the DEIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions; *Vermont Yankee Nuclear Power Com. v. NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the DEIS stage but are not raised until after completion of the Final Environmental Impact Statement (FEIS) may be waived or dismissed by the courts; *City of Angoon v. Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc., v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the three-month comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the FEIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed actions, comments on the DEIS should be as specific as possible. It is also helpful if comments refer to specific pages or

chapters of the DEIS. Comments may also address the adequacy of the DEIS or the merits of the alternatives formulated and discussed in the statements. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

After the comment period ends on the DEIS, comments will be analyzed, considered, and responded to by the Forest Service in preparing the Final EIS. The FEIS is scheduled to be completed in December 2003. The responsible officials will consider the comments, responses, environmental consequences discussed in the FEIS, and applicable laws, regulations, and policies in making decisions regarding these revisions. The responsible official will document his decision and reasons for the decision in a Record of Decision for the revised Management Plan. The decision will be subject to appeal in accordance with 36 CFR 217.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909-15, section 21.2)

Dated: July 19, 2002.

Richard C. Stem,

Deputy Regional Forester, Resources, Rocky Mountain Region.

[FR Doc. 02-21258 Filed 8-20-02; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Deschutes Provincial Advisory Committee (PAC); Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Deschutes Provincial Advisory Committee will meet on September 11-12, 2002. The first day is a field trip to the Dilman project on the Deschutes River to view implementation of activities related to forest health and dispersed recreation on the Deschutes National Forest. The second day will be a business meeting beginning 9 a.m. and ending 4 p.m. at the La Pine Library at 16425 1st St. in La Pine, Oregon. Topics include Northwest Forest Plan Monitoring, Deschutes National Forest Recreation Strategy, Upper Deschutes Resource Management Plan, Hosmer, Subcommittee updates/Round Robin, and a Public Forum from 3-3:30 p.m.

FOR FURTHER INFORMATION CONTACT:

Chris Mickle, Province Liaison, USDA, Bend-Ft. Rock Ranger District, 1230 NE. 3rd., Bend, OR, 97701, Phone (541) 383-4769.

Dated: August 14, 2002.

Leslie A.C. Weldon,

Forest Supervisor.

[FR Doc. 02-21217 Filed 8-20-02; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Lake County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Lake County Resource Advisory Committee (RAC) will hold a meeting.

DATES: The meeting will be held on September 19, 2002, from 3 p.m. to 6 p.m.

ADDRESSES: The meeting will be held at the Lake County Board of Supervisor's Chambers at 255 North Forbes Street, Lakeport.

FOR FURTHER INFORMATION CONTACT:

Debbie McIntosh, Committee Coordinator, USDA, Mendocino National Forest, Upper Lake Ranger District, 10025 Elk Mountain Road, Upper Lake, CA 95485. (707) 275-2361; e-mail dmcintosh@fs.fed.us.

SUPPLEMENTARY INFORMATION: Agenda items to be covered include: (1) Roll Call/Establish Quorum; (2) Review and Approval of the Minutes of the August 8, 2002 Meeting; (3) Finalize business for 2002; (4) Discuss/revise evaluation criteria for projects; (5) Evaluate Committee Membership; (6) Discussion on Chair Position for 2003; (7) Discussion on Next Meeting Date; and (8) Discuss Project Cost Accounting USFS/County of Lake; (9) Recommend Projects for 2003; (10) Public Comment period. The meeting is open to the public. Public input opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Dated: August 14, 2002.

Blaine P. Baker,

Designated Federal Officer.

[FR Doc. 02-21260 Filed 8-20-02; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 32-2002]

Foreign-Trade Zone 219—Yuma, Arizona; Application for Expansion

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Yuma County Airport Authority, Inc., grantee of Foreign-Trade Zone 219, requesting authority to expand FTZ 219, Yuma, Arizona, to include an additional site within the San Luis Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on August 14, 2002.

FTZ 219 was approved by the Board on April 2, 1997 (Board Order 874, 62 FR 17580, 4/10/97), and expanded on April 5, 2001 (Board Order 1161, 66 FR 19422, 4/16/01). The zone project currently consists of two parcels (125 acres) within the Yuma International Airport complex (Site 1), 2191 East 32nd Street, Yuma.

The applicant is now requesting authority to expand the general-purpose zone to include an additional site (95 acres) in Yuma: *Proposed Site 2* (95 acres)—Yuma Commerce Center, approximately 5 miles east of the Yuma International Airport on Business Loop Interstate 8. The site is owned by the Ingold Family Limited Partnership/Sun River Investment Properties. No specific manufacturing authority is being requested at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the following addresses:

1. Submission via Express/Package Delivery Services: Foreign-Trade Zones Board U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099 14th Street, NW, Washington, DC 20005; or

2. Submissions via the U.S. Postal Service: Foreign-Trade Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Avenue, NW, Washington, DC 20230.

The closing period for their receipt is October 21, 2002. Rebuttal comments in

response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to November 4, 2002).

A copy of the application and accompanying exhibits will be available during this time for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at address Number 1 listed above, and at the Yuma Main Library, 350 South 3rd Avenue, Yuma, Arizona 85364.

Dated: August 14, 2002.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 02-21328 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 31-2002]

Foreign-Trade Zone 86—Tacoma, Washington: Expansion of Manufacturing Authority—Subzone 86E; Matsushita Kotobuki Electronics Industries of America, Inc. (20- and 27-inch Television/Video Cassette Recorder/DVD Combination Units)

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Port of Tacoma, Washington, grantee of FTZ 86, requesting on behalf of Matsushita Kotobuki Electronics Industries of America, Inc. (MKA), to expand the scope of manufacturing authority under zone procedures within Subzone 86E, at the MKA facilities in Vancouver, Washington. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR part 400). It was formally filed on August 12, 2002.

Subzone 86E was approved by the Board in 2000 at four sites in Vancouver, Washington (five buildings and two trailers, 427,300 sq. ft. total). Authority was granted for the manufacture of 9- and 13-inch television/video cassette recorder/DVD combination units (Board Order 1176, 66 FR 32933, 6/19/2001).

MKA is now proposing to expand the scope of manufacturing activity conducted under zone procedures at Subzone 86E to include 20-inch flat and round screen television/video cassette recorder/DVD combination units and 27-inch flat screen television/video cassette recorder/DVD combination units. The finished products would have duty rates of 3.9% *ad valorem*. Additional foreign-sourced materials

under the proposed expanded scope would include 20-inch flat cathode ray tubes, 20-inch round cathode ray tubes, and 27-inch flat cathode ray tubes. Duty rates on those components are currently 15% *ad valorem*.

Expanded subzone authority would exempt MKA from Customs duty payments on the aforementioned foreign components when used in export production. On its domestic sales, MKA would be able to choose the lower duty rate that applies to the finished products for the foreign components, when applicable.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the following addresses:

1. Submissions via Express/Package Delivery Services: Foreign-Trade-Zones Board, U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099 14th St. NW., Washington, DC 20005; or

2. Submissions via the U.S. Postal Service: Foreign-Trade-Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Ave. NW., Washington, DC 20230.

The closing period for their receipt is October 21, 2002. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to November 4, 2002. A copy of the application and accompanying exhibits will be available for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at address Number 1 listed above, and at the U.S. Department of Commerce Export Assistance Center, One World Trade Center, 121 SW Salmon Street, Suite 242, Portland, OR 97204.

Dated: August 13, 2002.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 02-21327 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Closed Meeting of the U.S. Automotive Parts Advisory Committee (APAC)

AGENCY: International Trade Administration, Commerce.

ACTION: Announcement of meeting.

SUMMARY: The APAC will have a closed meeting on September 9, 2002, at the U.S. Department of Commerce to discuss U.S.-made automotive parts sales in Japanese and other Asian markets.

DATES: September 9, 2002.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Reck, U.S. Department of Commerce, Room 4036, Washington, DC 20230, telephone: 202-482-1418.

SUPPLEMENTARY INFORMATION: The U.S. Automotive Parts Advisory Committee (the "Committee") advises U.S. Government officials on matters relating to the implementation of the Fair Trade in Automotive Parts Act of 1998 (Public Law 105-261). The Committee: (1) Reports to the Secretary of Commerce on barriers to sales of U.S.-made automotive parts and accessories in Japanese and other Asian markets; (2) reviews and considers data collected on sales of U.S.-made auto parts and accessories in Japanese and other Asian markets; (3) advises the Secretary of Commerce during consultations with other Governments on issues concerning sales of U.S.-made automotive parts in Japanese and other Asian markets; and (4) assists in establishing priorities for the initiative to increase sales of U.S.-made auto parts and accessories to Japanese markets, and otherwise provide assistance and direction to the Secretary of Commerce in carrying out the intent of that section; and (5) assists the Secretary of Commerce in reporting to Congress by submitting an annual written report to the Secretary on the sale of U.S.-made automotive parts in Japanese and other Asian markets, as well as any other issues with respect to which the Committee provides advice pursuant to its authorizing legislation. At the meeting, committee members will discuss specific trade and sales expansion programs related to automotive parts trade policy between the United States and Japan and other Asian markets.

The Acting Assistant Secretary for Administration, with the concurrence of the General Counsel formally determined on August 14, 2002, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, that the September 9th meeting of the Committee and of any subcommittee thereof, dealing with privileged or confidential commercial information may be exempt from the provisions of the Act relating to open meeting and public participation therein because these items are concerned with matters that are within the purview of 5 U.S.C. 552b (c)(4) and (9)(B). A copy of the Notice of Determination is available for

public inspection and copying in the Department of Commerce Records Inspection Facility, Room 6020, Main Commerce.

Dated: August 16, 2002.

Henry Misisco,

Director, Office of Automotive Affairs.

[FR Doc. 02-21305 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 081202D]

Atlantic Highly Migratory Species; Advisory Panels

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for nominations.

SUMMARY: NMFS solicits nominations for the Highly Migratory Species (HMS) advisory panel (AP) and the Billfish AP, and announces a joint meeting tentatively for November 2002, in Silver Spring, MD. The purpose of the AP's will be to assist NMFS in the collection and evaluation of information relevant to modification or amendment of the fisheries management plan for Atlantic tunas, swordfish, and sharks (HMS FMP) and to modification of the Billfish FMP Amendment. The AP will include representatives from all interests in HMS fisheries and billfish fisheries, respectively.

DATES: Nominations must be submitted on or before October 7, 2002.

ADDRESSES: Nominations and comments on Statement of Organization, Practices and Procedures revision recommendations should be submitted in writing to Chris Rogers, Chief, Highly Migratory Species Division, NMFS, 1315 East-West Highway, Silver Spring, MD, 20910. Nominations may be submitted by fax; 301-713-1917.

FOR FURTHER INFORMATION CONTACT: Othel Freeman or Carol Douglas (301) 713-2347.

SUPPLEMENTARY INFORMATION:

Introduction

In accordance with the Magnuson-Stevens Fishery Conservation and Management Act, (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.*, as amended by the Sustainable Fisheries Act, Public Law 104-297, Advisory Panels (AP) have been established to consult with NMFS in the collection and evaluation of information relevant to the HMS FMP

(April 1999) and the Billfish FMP Amendment (April 1999). Nominations are being sought to fill one third of the posts of the HMS AP for three year appointments, and one half of the posts of the Billfish AP for two year appointments. The nomination process and appointments are required by the Statement of Organization, Practices and Procedures (SOPP) for each AP.

The purpose of the HMS AP is to advise and assist the Secretary of Commerce (Secretary) in the collection and evaluation of information relevant to any amendment to the HMS FMP (April 1999). The HMS AP evaluates future management options for Atlantic tunas, swordfish and sharks under the requirements of the Magnuson-Stevens Act.

The purpose of the Billfish AP is to advise and assist the Secretary in the collection and evaluation of information relevant to any amendment to the Billfish FMP. The Billfish AP evaluates future management options for Atlantic billfish under the requirements of the Magnuson-Stevens Act.

Procedures and Guidelines

A. Procedures for Appointing the Advisory Panels

Individuals with definable interests in the recreational and commercial fishing and related industries, environmental community, academia, governmental entities and non-governmental organizations will be considered for membership in the AP.

Nominations are invited from all individuals and constituent groups. The nomination should include:

1. The name of the applicant or nominee and a description of their interest in highly migratory species (HMS) or one species in particular from among sharks, swordfish, tunas and billfish;
2. A statement of background and/or qualifications;
3. The AP to which the applicant seeks appointment;
4. A written commitment that the applicant or nominee shall actively participate in good faith in the tasks of the AP.

Tenure for the HMS AP:

Member tenure will be for 3 years, with one third of the members' terms expiring on the last day of each calendar year. All appointments will be for 3 years (36 months).

Tenure for the Billfish AP:

Member tenure will be for 2 years, with one half of the terms expiring on the last day of each calendar year. All appointments will be for 2 years (24 months).

B. Participants

The HMS AP consists of not less than twenty-two (22) members who are knowledgeable about the pelagic fisheries for all Atlantic HMS species. The Billfish AP consists of not less than eight (8) members who are knowledgeable about the pelagic fisheries for all billfish species. Nominations for each AP will be accepted to allow representation from recreational and commercial fishing interests, the conservation community, and the scientific community.

NMFS does not believe that each potentially affected organization or individual must necessarily have its own representative, but each area of interest must be adequately represented. The intent is to have a group that, as a whole, reflects an appropriate and equitable balance and mix of interests given the responsibilities of each AP. Criteria for membership include one or more of the following: (a) Experience in the recreational fishing industry involved in catching swordfish, tunas, billfish, or sharks; (b) experience in the commercial fishing industry for HMS; (c) experience in fishery-related industries (marinas, bait and tackle shops); (d) experience in the scientific community working with HMS; (e) representation of a private, non-governmental, regional, (non-Federal) state, national, or international organization representing marine fisheries, environmental, governmental or academic interests dealing with HMS.

Five (5) additional members of the AP include one voting representative each of the New England Fishery Management Council, the Mid-Atlantic Fishery Management Council, the South Atlantic Fishery Management Council, the Gulf of Mexico Fishery Management Council, and the Caribbean Fishery Management Council. The AP also includes twenty-two (22) ex-officio participants: twenty (20) representatives of the constituent states and two (2) representatives of the constituent interstate commissions; the Atlantic States Marine Fisheries Commission and the Gulf States Marine Fisheries Commission.

NMFS will provide the necessary administrative support, including technical assistance, for the AP. However, NMFS will not compensate participants with monetary support of any kind. Depending on availability of funds members may be reimbursed for travel costs related to the AP meetings.

C. Tentative Schedule

Meetings of each AP will be held as frequently as necessary but are routinely held once each year in the Spring. Often the meetings are held jointly, and may be held in conjunction with other advisory panel meetings or public hearings. The meeting is tentatively scheduled for November 2002, in Silver Spring, MD. This meeting is being held in addition to the routinely held Spring meeting.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: August 15, 2002.

Virginia M. Fay,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 02-21315 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 081502B]

New England Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Enforcement Committee and Advisory Panel and its Vessel Monitoring Systems (VMS) Committee in September, 2002 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from these groups will be brought to the full Council for formal consideration and action, if appropriate.

DATES: The meetings will be held on September 4 and 5, 2002. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meetings will be held at the New England Fishery Management Council Office, 50 Water Street, Mill 12, Newburyport, MA 01950; telephone: (978) 465-0492.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; (978) 465-0492.

SUPPLEMENTARY INFORMATION:

Meeting Dates and Agendas

Wednesday, September 4, 2002, at 9 a.m.—Joint Enforcement Committee and Advisory Panel Meeting.

The committee will review federal vessel permit issues associated with the Atlantic herring fishery and requiring fishermen to have a valid VMS number prior to issuance of the permit. This would be consistent with previous federal fisheries that require VMS. They will also discuss prohibiting fishermen with federal vessel permits from selling fish to unlicensed dealers. Current regulations prohibit dealers without permit from buying fish from federally permitted vessels.

Also included in the agenda will be review of the enforceability of the following: alternatives for Multispecies Amendment 13; draft enforcement analysis for scallops; general category landings restriction, particularly those in the state-waters only exemption for scallops; review of species ID guide for skates and its utility for enforcement as well as proposed prohibitions on possession, landing, sale and recommendations for tolerances on prohibitions and/or possession limits to account for mis-identification of skates. The committee will also discuss whether to increase advisory panel membership.

Thursday, September 5, 2002, at 9:30 a.m.—Vessel Monitoring System Committee Meeting.

Location: New England Fishery Management Council Office, 50 Water Street, Mill 12, Newburyport, MA 01950; telephone: (978) 465-0492.

The committee will discuss the concept of using automated vessel monitoring systems in New England fisheries. The agenda will include discussion of current VMS performance, alternative tracking devices now available, future expansion of VMS programs and VMS use for other management measures. The committee also may discuss other business.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting dates.

Dated: August 15, 2002.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 02-21309 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 081502F]

New England Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scallop Oversight Committee in September, 2002. Recommendations from the committee will be brought to the full Council for formal consideration and action, if appropriate.

DATES: The meeting will held on Monday, September 9, 2002, at 1 p.m.

ADDRESSES: The meeting will be held at Providence Biltmore, 11 Dorrance Street, Kennedy Plaza, Providence, RI 02903; telephone: (401) 421-0700.

Council address: New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION: The committee will meet to develop recommendations for approval of final alternatives in the annual adjustment to the Scallop Fishery Management Plan (FMP) (Framework Adjustment 15 to the FMP); options under consideration for the 2003 fishing year include but are not limited to: an adjustment to the annual day-at-sea allocations for vessels with limited access permits, continuing the controlled access program for one or both of the Hudson Canyon and VA/NC Areas, and a day-at-sea tradeoff exemption procedure. The committee will also review the Habitat Committee's recommendations for alternatives in Amendment 10 and may develop advice for the September 10-12, 2002 Council meeting. Other business may be taken up as needed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal

action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting dates.

Dated: August 15, 2002.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 02-21313 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 081502E]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Gulf of Alaska (GOA) and Bering Sea/Aleutian Islands (BS/AI) Groundfish Plan Team meetings.

SUMMARY: The North Pacific Fishery Management Council's (Council) GOA and BS/AI Groundfish Plan Team will meet in Alaska.

DATES: The meeting will be held on September 9-10, 2002.

ADDRESSES: The Groundfish Plan Teams will meet at the Alaska Fishery Science Center, 7600 Sand Point Way NE, Bldg. 4, Seattle, WA 98115.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501-2252.

FOR FURTHER INFORMATION CONTACT: Council Staff: 907-271-2809.

SUPPLEMENTARY INFORMATION: On Monday, the 9th of September at 1 p.m., the Groundfish Plan Teams will meet at the Alaska Fishery Science Center. Items to be discussed include, Status of DPSEIS, SSL Protection Measures, Ecosystem Chapter, Other Species update, ESA listings. BS/AI will review preliminary drafts of Arrowtooth, Eastern Bering Sea Pollock and Atka

mackerel. GOA will review a preliminary draft of pollock hydroacoustic survey results, assessment update.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, 907-271-2809, at least 5 working days prior to the meeting date.

Dated: August 15, 2002.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 02-21312 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 081502H]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of committee meeting.

SUMMARY: The North Pacific Fishery Management Council's (Council) Gulf of Alaska Working Group will meet in Kodiak, AK.

DATES: The meeting will be held on September 19-21, 2002.

ADDRESSES: The meeting will be held at the Best Western Kodiak Inn, 236 Rezanof Drive, in the Harbor Room, Kodiak, AK 99615.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501-2252.

FOR FURTHER INFORMATION CONTACT: Council staff: 907-271-2809.

SUPPLEMENTARY INFORMATION: On Thursday, September 19th, the committee will meet starting at 1 p.m.

through noon on Saturday, September 21st, to review staff discussion papers on a preliminary data report, rockfish bycatch, converting halibut trawl bycatch into longline or pot directed fishery quota shares, the effects of an extended groundfish fishing season on halibut bycatch, alternative approaches to rationalizing Gulf of Alaska groundfish fisheries, and additional proposals for elements and options for analysis. An update on the public scoping process will be presented. Opportunities for public comment will be scheduled each day.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, 907-271-2809, at least 5 working days prior to the meeting date.

Dated: August 16, 2002.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 02-21314 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 081502C]

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Council) and its advisory bodies will hold public meetings.

DATES: The Council and its advisory bodies will meet September 7-13, 2002. The Council meeting will begin on Tuesday, September 10, at 10 a.m., reconvening each day through Friday. All meetings are open to the public, except a closed session will be held from 8 a.m. until 10 a.m. on Tuesday, September 10 to address litigation and personnel matters. The Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES: The meetings will be held at the DoubleTree Hotel Columbia River, 1401 N Hayden Island Drive, Portland, OR 97217; telephone: 503-283-2111.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Dr. Donald O. McIsaac, Executive Director; telephone: 503-820-2280 or 866-806-7204.

SUPPLEMENTARY INFORMATION: The following items are on the Council agenda, but not necessarily in this order. All items listed are subject to potential Council action.

A. Call to Order

1. Opening Remarks, Introductions
2. Council Member Appointments
3. Roll Call
4. Executive Director's Report
5. Approve Agenda
6. Approve March and April Minutes

B. Habitat Issues

Essential Fish Habitat Issues

C. Groundfish Management

1. NMFS Report on Groundfish Management
2. Final Harvest Levels and Other Specifications for 2003
3. Adoption of 2003 Groundfish Management Measures

4. Status of Fisheries and Inseason Adjustments

5. Exempted Fishing Permits (EFP): Update and New Proposals

6. Groundfish Programmatic and Essential Fish Habitat FMP Environmental Impact Statements

7. Update on Amendment 16-Rebuilding Plans

8. Groundfish Stock Assessment Priorities for 2003

9. Amendment 17-Multi-Year Management

10. Scoping for Delegation of Nearshore Management Authority

D. Salmon Management

1. NMFS Report
2. Update of Ongoing Fisheries
3. Scientific and Statistical Committee Methodology Review Priorities

E. Marine Reserves

1. Marine Reserve Proposals for Channel Island National Marine Sanctuary
2. Update on Marine Reserves Processes

F. Pacific Halibut Management

1. Status of 2002 Pacific Halibut Fisheries
2. Proposed Changes to the Catch Sharing Plan and Annual Regulations

G. Coastal Pelagic Species Management

1. NMFS Report
2. Pacific Sardine Fishery Update

H. Administrative and Other Matters

1. Legislative Matters
2. Financial Matters
3. Appointments to Advisory Bodies, Standing Committees, and Other Forums
4. Council Staff Work Load Priorities
5. November 2002 Council Meeting Draft Agenda

SCHEDULE OF ANCILLARY MEETINGS

SATURDAY, SEPTEMBER 7, 2002

Groundfish Management Team

SUNDAY, SEPTEMBER 8, 2002

Groundfish Management Team

MONDAY, SEPTEMBER 9, 2002

Council Secretariat

Groundfish Advisory Subpanel

Groundfish Management Team

Scientific and Statistical Committee

Salmon Advisory Subpanel

Salmon Technical Team

Habitat Committee

1 p.m.

8 a.m.

8 a.m.

8 a.m.

8 a.m.

8 a.m.

10 a.m.

10 a.m.

10 a.m.

SCHEDULE OF ANCILLARY MEETINGS—Continued

Legislative Committee	10 a.m.
Budget Committee	1 p.m.
<i>TUESDAY, SEPTEMBER 10, 2002</i>	
Council Secretariat	7 a.m.
California State Delegation	7 a.m.
Oregon State Delegation	7 a.m.
Washington State Delegation	7 a.m.
Groundfish Advisory Subpanel	8 a.m.
Groundfish Management Team	8 a.m.
Scientific and Statistical Committee	8 a.m.
Salmon Advisory Subpanel	8 a.m.
Salmon Technical Team	As necessary
Enforcement Consultants	Immediately following Council Session
<i>WEDNESDAY, SEPTEMBER 11, 2002</i>	
Council Secretariat	7 a.m.
California State Delegation	7 a.m.
Oregon State Delegation	7 a.m.
Washington State Delegation	7 a.m.
Coastal Pelagic Species Advisory Subpanel	10 a.m.
Groundfish Advisory Subpanel	As necessary
Groundfish Management Team	As necessary
Salmon Advisory Subpanel	As necessary
Salmon Technical Team	As necessary
Enforcement Consultants	As necessary
<i>THURSDAY, SEPTEMBER 12, 2002</i>	
Council Secretariat	7 a.m.
California State Delegation	7 a.m.
Oregon State Delegation	7 a.m.
Washington State Delegation	7 a.m.
Groundfish Advisory Subpanel	As necessary
Salmon Advisory Subpanel	As necessary
Salmon Technical Team	As necessary
Enforcement Consultants	As necessary
<i>FRIDAY, SEPTEMBER 13, 2002</i>	
Council Secretariat	7 a.m.
California State Delegation	7 a.m.
Oregon State Delegation	7 a.m.
Washington State Delegation	7 a.m.
Enforcement Consultants	As necessary

Although non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503)820-2280 or (866)806-7204 at least 5 days prior to the meeting date.

Dated: August 15, 2002.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 02-21310 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[I.D. 081502D]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Coastal Pelagic Species Advisory Subpanel (CPSAS) will hold a conference call, which is open to the public.

DATES: The CPSAS will convene via conference call Friday, September 6, 2002, from 1 p.m. until business for the day is completed.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** for a list of public listening station locations.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Mr. Dan Waldeck, Pacific Fishery Management Council; telephone: (503) 820-2280.

SUPPLEMENTARY INFORMATION: Public listening stations will be available at the following locations:

1. National Marine Fisheries Service, 501 W Ocean Blvd., Long Beach, CA 90802, (562) 980-4000, Contact: Jim Morgan;

2. California Department of Fish and Game, 1933 Cliff Drive, Suite 9, Santa Barbara, CA 93109, (805) 568-1231, Contact: Marija Vojkovich;

3. California Department of Fish and Game, 20 Lower Ragsdale Drive, Suite 100, Monterey, CA 93940, (831) 649-2870, Contact: Travis Tanaka; and

4. Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220-1384, (503) 820-2280, Contact: Dan Waldeck.

The purpose of the work session is to prepare CPSAS comments to the Council regarding two matters, (1) potential collateral impacts on CPS fisheries from proposed regulations for the 2003 West Coast groundfish fishery, and (2) recommendations from the

Council's Ad Hoc Marine Reserves Policy Committee regarding marine reserves in California state waters. Both of these matters are due for final Council consideration at the September 2002 Council meeting. This conference call is intended to provide the CPSAS opportunity to consider these matters and develop recommendations for the Council.

Although nonemergency issues not contained in the CPSAS meeting agenda may come before the CPSAS for discussion, those issues may not be the subject of formal CPSAS action during this meeting. CPSAS action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the CPSAS's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 820-2280 at least 5 days prior to the meeting date.

Dated: August 16, 2002.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 02-21311 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 080602D]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Highly Migratory Species Plan Development Team (HMSPDT) will hold a work session, which is open to the public.

DATES: The HMSPDT will meet Wednesday, September 4, 2002 from 8 a.m. until 5 p.m.; and Thursday, September 5, 2002 from 8 a.m. until business for the day is completed.

ADDRESSES: The work session will be held at the Hubbs-Sea World Research

Institute, Auditorium, 2595 Ingraham Street, San Diego, CA 92109; telephone: (619) 226-3870.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Mr. Dan Waldeck, Pacific Fishery Management Council, telephone: (503) 820-2280.

SUPPLEMENTARY INFORMATION: The primary purpose of the work session is to review comments on the draft fishery management plan (FMP) for West Coast highly migratory species (HMS) and revise the FMP accordingly for presentation to the Council at the November Council meeting. The HMS FMP is scheduled for final Council action in November 2002.

Although nonemergency issues not contained in the HMSPDT meeting agenda may come before the HMSPDT for discussion, those issues may not be the subject of formal HMSPDT action during this meeting. HMSPDT action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the HMSPDT's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 820-2280 at least 5 days prior to the meeting date.

Dated: August 9, 2002.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 02-21317 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-22-S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textiles and Textile Products Produced or Manufactured in Thailand

August 16, 2002.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: August 21, 2002.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927-5850, or refer to the U.S. Customs website at <http://www.customs.gov>. For information on embargoes and quota reopenings, refer to the Office of Textiles and Apparel website at <http://otexa.ita.doc.gov>.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted for swing and carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the **CORRELATION:** Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 66 FR 65178, published on December 18, 2001). Also see 66 FR 63036, published on December 4, 2001.

James C. Leonard III,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

August 16, 2002.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 27, 2001, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Thailand and exported during the twelve-month period which began on January 1, 2002 and extends through December 31, 2002.

Effective on August 21, 2002, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit ¹
Levels in Group I	
300	6,683,636 kilograms.
301-O ²	1,531,953 kilograms.

Category	Adjusted twelve-month limit ¹
313-O ³	30,921,420 square meters.
619	10,777,870 square meters.
620	10,940,248 square meters.
Group II	
Sublevels in Group II	
338/339	2,742,895 dozen.
347/348	1,303,280 dozen.

¹ The limits have not been adjusted to account for any imports exported after December 31, 2001.

² Category 301-O: only HTS numbers 5205.21.0020, 5205.21.0090, 5205.22.0020, 5205.22.0090, 5205.23.0020, 5205.23.0090, 5205.24.0020, 5205.24.0090, 5205.26.0020, 5205.26.0090, 5205.27.0020, 5205.27.0090, 5205.28.0020, 5205.28.0090, 5205.41.0020, 5205.41.0090, 5205.42.0020, 5205.42.0090, 5205.43.0020, 5205.43.0090, 5205.44.0020, 5205.44.0090, 5205.46.0020, 5205.46.0090, 5205.47.0020, 5205.47.0090, 5205.48.0020 and 5205.48.0090.

³ Category 313-O: all HTS numbers except 5208.52.3035, 5208.52.4035 and 5209.51.6032.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,
James C. Leonard III,
Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 02-21276 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-DR-S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Denial of Short Supply Request under the United States - Caribbean Basin Trade Partnership Act (CBTPA)

August 15, 2002.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Denial of the request alleging that certain 100 percent cotton yarn-dyed flannel fabrics, for use in apparel articles, cannot be supplied by the domestic industry in commercial quantities in a timely manner.

SUMMARY: On June 11, 2002, the Chairman of CITA received a request from Intradeco Corporation of Miami, Florida alleging that certain fabrics, classified under subheading 5208.43.00 of the Harmonized Tariff Schedule of the United States (HTSUS), cannot be supplied by the domestic industry in commercial quantities in a timely manner. It requested that apparel of such fabrics be eligible for preferential treatment under the CBTPA. Based on

currently available information, CITA has determined that these subject fabrics can be supplied by the domestic industry in commercial quantities in a timely manner and therefore denies the request.

FOR FURTHER INFORMATION CONTACT: For Further Information Contact: Richard Stetson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Section 213(b)(2)(A)(v)(II) of the Caribbean Basin Economic Recovery Act, as added by Section 211(a) of the CBTPA; Section 6 of Executive Order No. 13191 of January 17, 2001.

BACKGROUND:

The CBTPA provides for quota- and duty-free treatment for qualifying textile and apparel products. Such treatment is generally limited to products manufactured from yarns or fabrics formed in the United States or a beneficiary country. The CBTPA also provides for quota- and duty-free treatment for apparel articles that are both cut (or knit-to-shape) and sewn or otherwise assembled in one or more CBTPA beneficiary countries from fabric or yarn that is not formed in the United States or a CBTPA beneficiary country, if it has been determined that such fabric or yarn cannot be supplied by the domestic industry in commercial quantities in a timely manner. In Executive Order No. 13191, the President delegated to CITA the authority to determine whether yarns or fabrics cannot be supplied by the domestic industry in commercial quantities in a timely manner under the CBTPA. On March 6, 2001, CITA published procedures that it will follow in considering requests. (66 FR 13502).

On June 11, 2002, the Chairman of CITA received a request from Intradeco Corporation of Miami, Florida alleging that certain 100 percent cotton yarn-dyed flannel fabrics, classified under subheading 5208.43.00 of the HTSUS, of construction 2X2 twill weave 64X54, cannot be supplied by the domestic industry in commercial quantities in a timely manner. It requested that apparel of such fabric that are both cut and sewn or otherwise assembled in one or more CBTPA beneficiary countries be eligible for preferential treatment under the CBTPA.

On June 17, 2002, CITA solicited public comments regarding this request, particularly with respect to whether these fabrics can be supplied by the domestic industry in commercial quantities in a timely manner. On July

5, 2002, CITA and the Office of the U.S. Trade Representative offered to hold consultations with the relevant Congressional committees. We also requested the advice of the U.S. International Trade Commission and the relevant Industry Sector Advisory Committees.

CITA has determined that certain 100 percent cotton yarn-dyed flannel fabrics, classified under subheading 5208.43.00 of the HTSUS, of construction 2X2 twill weave 64X54, used in apparel, can be supplied by the domestic industry in commercial quantities in a timely manner. On the basis of currently available information, including review of the request, public comment and advice received, and its understanding of the industry, CITA has determined that there is domestic capacity to supply these fabrics. Intradeco's request is denied.

James C. Leonard III,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 02-21223 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-DR-S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Request for Public Comment on Short Supply Petition under the North American Free Trade Agreement (NAFTA)

August 15, 2002.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Request for public comments concerning a petition for a modification of the NAFTA rules of origin for certain products made of yarn from combed fine animal hair.

SUMMARY: On July 12, 2002, the Chairman of CITA received a petition from Amicale Industries, Inc. (Amicale) alleging that yarn of combed fine animal hair, classified in subheading 5108.20.60 of the Harmonized Tariff Schedule of the United States (HTSUS), cannot be supplied by the NAFTA region in commercial quantities in a timely manner and requesting that the President proclaim a modification of the NAFTA rules of origin. Amicale requests that the NAFTA rules of origin for woven fabrics of subheadings, 5112.11.60, 5112.19.95, and for men's and women's apparel of subheadings 6203.11.30, 6203.11.90, 6203.21.30, 6203.21.90, 6203.31.90, 6203.41.18, 6204.11.00, 6204.21.00, 6204.31.10, 6204.31.20, 6204.51.00, and 6204.61.90,

be modified to allow for the use of non-North American origin yarn of subheading 5108.20.60. Such a proclamation may be made only after reaching agreement with the other NAFTA countries on the modification. CITA hereby solicits public comments on this petition, in particular with regard to whether yarn of combed fine animal hair classified under HTSUS subheading 5108.20.60 can be supplied by the domestic industry in commercial quantities in a timely manner. To be ensured full consideration, comments must be submitted by September 20, 2002, to the Chairman, Committee for the Implementation of Textile Agreements, Room 3001, United States Department of Commerce, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: For Further Information Contact: Richard Stetson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 USC 1854); Section 202(q) of the North American Free Trade Agreement Implementation Act (19 USC 3332(q)); Executive Order 11651 of March 3, 1972, as amended.

BACKGROUND:

Under the North American Free Trade Agreement (NAFTA), NAFTA countries are required to eliminate customs duties on textile and apparel goods that qualify as originating goods under the NAFTA rules of origin, which are set out in Annex 401 to the NAFTA. The NAFTA provides that the rules of origin for textile and apparel products may be amended through a subsequent agreement by the NAFTA countries. In consultations regarding such a change, the NAFTA countries are to consider issues of availability of supply of fibers, yarns, or fabrics in the free trade area and whether domestic producers are capable of supplying commercial quantities of the good in a timely manner. The Statement of Administrative Action (SAA) that accompanied the NAFTA Implementation Act stated that any interested person may submit to CITA a request for a modification to a particular rule of origin based on a change in the availability in North America of a particular fiber, yarn or fabric and that the requesting party would bear the burden of demonstrating that a change is warranted. The SAA provides that CITA may make a recommendation to the President regarding a change to a rule of origin for a textile or apparel

good. The NAFTA Implementation Act provides the President with the authority to proclaim modifications to the NAFTA rules of origin as are necessary to implement an agreement with one or more NAFTA country on such a modification.

On July 12, 2002, the Chairman of CITA received a petition from Amicale Industries, Inc. (Amicale) alleging that yarn of combed fine animal hair, classified in subheading 5108.20.60 of the Harmonized Tariff Schedule of the United States (HTSUS), cannot be supplied by the NAFTA region in commercial quantities in a timely manner and requesting that the President proclaim a modification of the NAFTA rules of origin. Amicale requests that the NAFTA rules of origin for woven fabrics of subheadings, 5112.11.60, 5112.19.95, and for men's and women's apparel of subheadings 6203.11.30, 6203.11.90, 6203.21.30, 6203.21.90, 6203.31.90, 6203.41.18, 6204.11.00, 6204.21.00, 6204.31.10, 6204.31.20, 6204.51.00, and 6204.61.90, be modified to allow for the use of non-North American origin yarn of subheading 5108.20.60. Such a proclamation may be made only after reaching agreement with the other NAFTA countries on the modification.

CITA is soliciting public comments regarding this request, particularly with respect to whether yarn of combed fine animal hair, classified in HTSUS subheading 5108.20.60, can be supplied by the domestic industry in commercial quantities in a timely manner. To be ensured full consideration, comments must be received no later than September 20, 2002. Interested persons are invited to submit six copies of such comments or information to the Chairman, Committee for the Implementation of Textile Agreements, Room 3100, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, DC 20230.

If a comment alleges that yarn of fine animal hair can be supplied by the domestic industry in commercial quantities in a timely manner, CITA will closely review any supporting documentation, such as a signed statement by a manufacturer of the yarn stating that it produces the yarn that is in the subject of the request, including the quantities that can be supplied and the time necessary to fill an order, as well as any relevant information regarding past production.

CITA will protect any business confidential information that is marked business confidential from disclosure to the full extent permitted by law. CITA will make available to the public non-confidential versions of the request and

non-confidential versions of any public comments received with respect to a request in room 3100 in the Herbert Hoover Building, 14th and Constitution Avenue, N.W., Washington, DC 20230. Persons submitting comments on a request are encouraged to include a non-confidential version and a non-confidential summary.

James C. Leonard III,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 02-21222 Filed 8-20-02; 8:45 am]

BILLING CODE 3510-DR-S

CONGRESSIONAL BUDGET OFFICE

Notice of Transmittal of Sequestration Update Report for Fiscal Year 2003 to the Congress and the Office of Management and Budget

Pursuant to section 254(b) of the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 904(b)), the Congressional Budget Office hereby reports that it has submitted its *Sequestration Update Report for Fiscal Year 2003* to the House of Representatives, the Senate and the Office of Management and Budget.

William J. Gainer,

Associate Director, Management, Congressional Budget Office.

[FR Doc. 02-21282 Filed 8-20-02; 8:45 am]

BILLING CODE 0701-02-M

DEPARTMENT OF DEFENSE

Department of the Army

Reserve Officers' Training Corps Program Subcommittee; Meeting

AGENCY: Department of the Army, DoD.

ACTION: Notice; date correction.

SUMMARY: The open meetings scheduled for June 25, 2002 from 8 a.m. to 5 p.m. and June 27, 2002 from 8 a.m. to 5 p.m. published in the **Federal Register** on May 24, 2002 (67 FR 36577) have been rescheduled. The open meeting will now be held on October 1, 2002 from 8 a.m. to 5 p.m. and on October 2, 2002 from 8 a.m. to 12 p.m. in Hampton, Virginia at the Radisson Hotel Hampton.

FOR FURTHER INFORMATION CONTACT: Commander, HQ U.S. Army Cadet Command, ATTN: ATCC-TT (Mrs. Johnson), Fort Monroe, VA 23651. Telephone number is (757) 788-4586.

SUPPLEMENTARY INFORMATION: This meeting is open to the public. Any interested person may attend, appear

before, or file statements with the committee.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 02-21306 Filed 8-20-02; 8:45 am]

BILLING CODE 3710-08-M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before October 21, 2002.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this

collection on the respondents, including through the use of information technology.

Dated: August 15, 2002.

John D. Tressler,

Leader, Regulatory Information Management Group, Office of the Chief Information Officer.

Federal Student Aid

Type of Review: Revision of a currently approved collection.

Title: Student Aid Report (SAR) (JS).

Frequency: Annually.

Affected Public: Individuals or household (primary).

Reporting and Recordkeeping Hour Burden:

Responses: 20,524,631.

Burden Hours: 4,871,526.

Abstract: The Student Aid Report (SAR) is used to notify all applicants of their eligibility to receive Federal student aid for postsecondary education. The form is submitted by the applicant to the institution of their choice.

Requests for copies of the proposed information collection request may be accessed from <http://edicsweb.ed.gov>, by selecting the "Browse Pending Collections" link and by clicking on link number 2097. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202-4651 or to the e-mail address Vivian.Reese@ed.gov. Requests may also be electronically mailed to the Internet address OCIO_RIMG@ed.gov or faxed to 202-708-9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Joe Schubart at (202) 708-9266. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. 02-21216 Filed 8-20-02; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL02-120-000]

Edison Mission Energy, Inc., Complainant v. PJM Interconnection L.L.C. and PJM Market Monitoring Unit, Respondents; Notice of Complaint

August 15, 2002.

Take notice that on August 14, 2002, Edison Mission Energy, Inc. filed a complaint against PJM Interconnection L.L.C. and the PJM Market Monitoring Unit objecting to the lack of confidentiality safeguards contained in the PJM Market Mitigation Plan that would protect the disclosure of confidential fuel cost information requested by the PJM Market Monitoring Unit.

Any person desiring to be heard or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. The answer to the complaint and all comments, interventions or protests must be filed on or before September 3, 2002. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, call (202)502-8222 or for TTY, (202) 208-1659. The answer to the complaint, comments, protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Linwood A. Watson, Jr.,

Deputy Secretary.

[FR Doc. 02-21270 Filed 8-20-02; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****[Project No. 184-065 California]****El Dorado Irrigation District; Notice of Public Meeting**

August 15, 2002.

The Federal Energy Regulatory Commission (Commission) is reviewing the application for a new license for the El Dorado Project (FERC No. 184), filed on February 22, 2000. The El Dorado Project, licensed to the El Dorado Irrigation District (EID), is located on the South Fork American River, in El Dorado, Alpine, and Amador Counties, California. The project occupies lands of the Eldorado National Forest.

The EID, several state and federal agencies, and several non-governmental agencies are working collaboratively with a facilitator to resolve certain issues relevant to this proceeding. This meeting is a part of that collaborative process.

On Friday, August 30, 2002, the Aquatics/Hydrology workgroup will meet from 9:00 a.m. until 4:00 p.m. The meeting will focus on hydrologic modeling of different operational alternatives for the project. We invite the participation of all interested governmental agencies, non-governmental organizations, and the general public in this meeting.

The meeting will be held at the Rancho Cordova Holiday Inn, located at 11131 Folsom Blvd., Rancho Cordova, California.

For further information, please contact Elizabeth Molloy at (202) 502-8771 or John Mudre at (202) 502-8902.

Linwood A. Watson, Jr.,*Deputy Secretary.*

[FR Doc. 02-21273 Filed 8-20-02; 8:45 am]

BILLING CODE 6717-01-P**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****[Docket No. EL02-119-000]****The Kroger Co., Complainant v. Dynegy Power Marketing, Inc., Respondent; Notice of Complaint**

August 15, 2002.

Take notice that on August 14, 2002, The Kroger Co. tendered for filing with the Federal Energy Regulatory Commission (Commission) a complaint against Dynegy Power Marketing, Inc. (Dynegy) seeking Commission action: to

declare the prices contained in four wholesale confirmations executed in Spring 2001 as unjust and unreasonable and contrary to the public interest; to set just and reasonable prices based on current market conditions; to establish a refund effective date within 60 days of filing of the complaint; and to initiate hearing procedures.

Any person desiring to be heard or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. The answer to the complaint and all comments, interventions or protests must be filed on or before September 13, 2002. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, call (202)502-8222 or for TTY, (202) 208-1659. The answer to the complaint, comments, protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Linwood A. Watson, Jr.,*Deputy Secretary.*

[FR Doc. 02-21269 Filed 8-20-02; 8:45 am]

BILLING CODE 6717-01-P**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission****[Docket No. PR02-20-000]****Union Light, Heat and Power Company; Notice of Petition for Rate Approval**

August 15, 2002.

Take notice that on July 18, 2002, Union Light, Heat and Power Company (Union) filed pursuant to section 284.123(b)(2) of the Commission's regulations, a petition for rate approval requesting that the Commission approve the proposed rates as fair and equitable

for transportation and storage services performed under section 311 of the Natural Gas Policy Act of 1978 (NGPA).

Union proposes to establish a monthly 100% reservation charge rate of \$0.3046 per Dekatherm of demand associated with a no-notice quality service to be rendered pursuant to its Order No. 63 blanket certificate issued on December 1, 1998, in Docket No. CP98-70-000.

Pursuant to section 284.123(b)(2)(ii), if the Commission does not act within 150 days of the date of this filing, the rates will be deemed to be fair and equitable and not in excess of an amount which interstate pipelines would be permitted to charge for similar transportation service. The Commission may, prior to the expiration of the 150 day period, extend the time for action or institute a proceeding to afford parties an opportunity for written comments and for the oral presentation of views, data, and arguments.

Any person desiring to participate in this rate proceeding must file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed with the Secretary of the Commission on or before August 22, 2002. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This petition for rate approval is on file with the Commission are available for public inspection. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For Assistance, call (202)502-8222 or for TTY, (202) 208-1659. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Linwood A. Watson, Jr.,*Deputy Secretary.*

[FR Doc. 02-21274 Filed 8-20-02; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. ER02-1423-004, et al.]

Midwest Independent Transmission System Operator, Inc., et al.; Electric Rate and Corporate Regulation Filings

August 13, 2002.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Midwest Independent Transmission System Operator, Inc.

[Docket Nos. ER02-1423-004 and ER02-1842-002]

Take notice that on August 5, 2002, the Midwest Independent Transmission System Operator, Inc. (the Midwest ISO), submitted certain revisions to the Joint Open Access Transmission Tariff of the Midwest Independent Transmission System Operator, Inc. for the Transmission System (Michigan) in compliance with the Federal Energy Regulatory Commission's (Commission) July 5, 2002 order in these proceedings. The Midwest ISO requests that these changes become effective May 1, 2002.

A copy of the filing was served upon the parties on the official Commission service lists established in these proceeding, on all affected state commissions, and on other affected parties.

Comment Date: August 26, 2002.

2. Conoco Gas & Power Marketing

[Docket No. ER02-1890-000]

Take notice that on July 31, 2002, Conoco Gas & Power Marketing, a Division of Conoco, Inc., tendered for filing a Notice of Withdrawal. This entity is no longer involved in power transactions.

Comment Date: August 23, 2002.

3. New York Independent System Operator, Inc.

[Docket No. ER02-1961-001]

Take notice that on August 5, 2002, the New York Independent System Operator, Inc. (NYISO) filed in this docket a response to the Commission's July 5, 2002 deficiency letter. The NYISO has requested an effective date of June 1, 2002 for the filing.

The NYISO has served a copy of this filing upon all parties that have executed service agreements under the NYISO's OATT and Services Tariff and on the electric utility regulatory agencies of New York, New Jersey and Pennsylvania, including, as directed in

the Deficiency Letter, a copy of this filing to all parties who have either requested or been granted intervention in these proceedings.

Comment Date: August 26, 2002.

4. Puget Sound Energy, Inc.

[Docket No. ER02-2012-001]

Take notice that on August 7, 2002, Puget Sound Energy, Inc. (Puget) submitted for filing, a revised Rate Schedule, a First Revised Service Agreement No. 1, which includes the Amendment No. 1 to the Agreement for the Installation of Electrical Facilities—South SeaTac filed on June 4, 2002. This First Revised Service Agreement No. 1 is effective May 17, 2002.

Comment Date: August 27, 2002.

5. Southaven Power, LLC

[Docket No. ER02-2056-000]

Take notice that on August 6, 2002, Southaven Power, LLC submitted a Notice of Withdrawal of the Request for Authorization to Amend Market-Based Rate Tariff filed June 10, 2002 in the above referenced docket.

Comment Date: August 26, 2002.

6. Green Country Energy, LLC

[Docket No. ER02-2057-000]

Take notice that on August 6, 2002, Green Country Energy, LLC, submitted a Notice of Withdrawal of the Request for Authorization to Amend Market-Based Rate Tariff filed in the above referenced docket on June 10, 2002.

Comment Date: August 26, 2002.

7. Cogentrix Energy Power Marketing, Inc.

[Docket No. ER02-2058-000]

Take notice that on August 6, 2002, Cogentrix Energy Power Marketing, Inc., submitted a Notice of Withdrawal of the Request for Authorization to Amend Market-Based Rate Tariff in the above referenced docket on June 10, 2002.

Comment Date: August 26, 2002.

8. Rathdrum Power, LLC

[Docket No. ER02-2059-000]

Take notice that on August 6, 2002, Rathdrum Power, LLC, submitted a Notice of Withdrawal of the Request for Authorization to Amend Market-Based Rate Tariff in the above referenced docket on June 10, 2002.

Comment Date: August 26, 2002.

9. Jackson County Power, LLC

[Docket No. ER02-2060-000]

Take notice that on August 6, 2002, Jackson County Power, LLC, submitted a Notice of Withdrawal of the Requests for Authorization to Amend Market-Based Rate Tariff in the above referenced docket on June 10, 2002.

Comment Date: August 26, 2002.

10. Caledonia Generating, LLC

[Docket No. ER02-2061-000]

Take notice that on August 6, 2002, Caledonia Generating, LLC, submitted a Notice of Withdrawal of the Request for Authorization to Amend Market-Based Rate Tariff filed in the above referenced docket on June 10, 2002.

Comment Date: August 26, 2002.

11. Quachita Power, LLC

[Docket No. ER02-2062-000]

Take notice that on August 6, 2002, Quachita Power, LLC, submitted a Notice of Withdrawal of the Request for Authorization to Amend Market-Based Rate Tariff filed in the above referenced docket on June 10, 2002.

Comment Date: August 26, 2002.

12. Cogentrix Lawrence County, LLC

[Docket No. ER02-2063-000]

Take notice that on August 6, 2002, Cogentrix Lawrence County, LLC, submitted a Notice of Withdrawal of the Request for Authorization to Amend Market-Based Rate Tariff in the above referenced docket on June 10, 2002.

Comment Date: August 26, 2002.

13. Southwestern Power Marketers, Inc.

[Docket No. ER02-2438-000]

Take notice that on August 6, 2002, Southwestern Power Marketers, Inc., has formally ceased operations. Please withdraw the market based tariff in Docket No. ER97-2529-000.

Comment Date: August 27, 2002.

14. Enerserve, L.C.

[Docket No. ER02-2439-000]

Take notice that on August 8, 2002, Enerserve, L.C. was closed. Enerserve, L.C. is requesting termination of the certificate authorizing to engage in wholesale electric power and energy transaction as a marketer.

Comment Date: August 29, 2002.

15. Alcoa Power Generating, Inc.

[Docket No. ER02-2440-000]

Take notice that on August 8, 2002, pursuant to Section 205 of the Federal Power Act and Section 35.15(a), 18 CFR 35.15(a) of the Commission's Regulations, Alcoa Power Generating, Inc. (APGI) filed with the Federal Energy Regulatory Commission a Notice of Termination of its Long-Term Agreement by and between APGI and Aquila Merchant Services, Inc., successor to Aquila Energy Marketing Corporation. Pursuant to Section 35.15(a) of the Commission's Regulations, APGI requests an effective date for this termination of August 9, 2002.

Comment Date: August 29, 2002.

16. Tucson Electric Power Company

[Docket No. ER02-2441-000]

Take notice that on August 8, 2002, Tucson Electric Power Company tendered for filing one (1) Umbrella Service Agreement (for short-term firm service) and one (1) Service Agreement (for non-firm service) pursuant to Part II of Tucson's Open Access Transmission Tariff, which was filed in Docket No. ER01-208-000.

The details of the service agreements are Umbrella Agreement for Short-Term Firm Point-to-Point Transmission Service dated as of August 2, 2002 by and between Tucson Electric Power Company and UBS AG, London Branch—FERC Electric Tariff Vol. No. 2, Service Agreement No. 200. No service has commenced at this time.

Form of Service Agreement for Non-Firm Point-to-Point Transmission Service dated as of August 2, 2002 by and between Tucson Electric Power Company and UBS AG, London Branch—FERC Electric Tariff Vol. No. 2, Service Agreement No. 201. No service has commenced at this time.

Comment Date: August 29, 2002.

Standard Paragraph

E. Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's web site at <http://www.ferc.gov> using the "RIMS" link, select "Docket #" and follow the instructions (call 202-208-2222 for assistance). Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the "e-Filing" link.

Linwood A. Watson, Jr.,
Deputy Secretary.

[FR Doc. 02-21266 Filed 8-20-02; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of FERC Staff Participation at MISO-PJM-SPP Single Market Design Forum Meeting

August 15, 2002.

The Federal Energy Regulatory Commission hereby gives notice that on August 22, 2002, members of its staff will attend the MISO-PJM-SPP Single Market Design Forum meeting, concerning the development of a joint and common wholesale energy market for the Midwest Independent Transmission System Operator, Inc. (MISO), PJM Interconnection (PJM) and Southwest Power Pool, Inc. (SPP) regions. The staff's attendance is part of the Commission's ongoing outreach efforts. The meeting is sponsored by MISO, PJM and SPP, and will be held on August 22, 2002, 10:00 a.m. at the Sheraton Suites International, 7032 Elm Road, Baltimore, MD 20240. This meeting is open to the public. The meeting may discuss matters at issue in Docket No. RM01-12-000, Remedying Undue Discrimination Through Open Access Transmission Service and Standard Electricity Market Design, and in Docket No. EL02-65-000, *et al.*, Alliance Companies, *et al.*

For more information, contact Mike Gahagan, Vice President, Chief Information Officer & Chief Strategic Officer, Midwest Independent Transmission System Operator, Inc. at (317) 249-5450, or Lawrence R. Greenfield, Senior Counsel, Federal Energy Regulatory Commission at (202) 502-6415 or lawrence.greenfield@ferc.gov.

Dated:

Linwood A. Watson, Jr.,
Deputy Secretary.

[FR Doc. 02-21271 Filed 8-20-02; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[AMS-FRL-7263-4]

California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption—Notice of Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA today, pursuant to section 209(b) of the Clean Air Act

(Act), 42 U.S.C. 7543(b), is granting California its request for a waiver of federal preemption, with the exceptions noted below, for its Onboard Refueling Vapor Recovery (ORVR) regulations. By letter dated July 22, 1997, the California Air Resources Board (CARB) requested that EPA grant California a waiver of federal preemption for its ORVR regulations which primarily incorporate EPA's ORVR regulations and with a phase-in commencing in 1998.

ADDRESSES: The Agency's Decision Document, containing an explanation of the Assistant Administrator's decision, as well as all documents relied upon in making that decision, including those submitted to EPA by CARB, are available at the EPA's Air and Radiation Docket and Information Center (Air Docket). The Air Docket Office is open from 8 to 4 p.m. Monday through Friday, at EPA, Air Docket (6102), Room M-1500, Waterside Mall, 401 M Street, SW., Washington, DC 20460. The reference number for this docket is A-97-38.

Electronic copies of this Notice and the accompanying Decision Document are available via the Internet on the Office of Transportation and Air Quality (OTAQ) website (<http://www.epa.gov/OTAQ>). Users can find these documents by accessing the OTAQ website and looking at the path entitled, "Regulations." This service is free of charge, except for any cost you already incur for Internet connectivity. The electronic **Federal Register** version of the Notice is made available on the day of publication on the primary website (<http://www.epa.gov/docs/fedrgstr/EPA-AIR>).

Please note that due to differences between the software used to develop the documents and the software into which the documents may be downloaded, changes in format, page length, etc., may occur.

FOR FURTHER INFORMATION CONTACT:

David J. Dickinson, Certification and Compliance Division, U.S. Environmental Protection Agency, Ariel Rios Building (6405J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Telephone: (202) 564-9256. Fax: (202) 565-2057. E-Mail address: Dickinson.David@EPA.GOV.

SUPPLEMENTARY INFORMATION: I have decided to grant California a waiver of Federal preemption pursuant to section 209(b) of the Act for amendments to its motor vehicle pollution control program for ORVR which incorporates (1) EPA's emission standards (0.20 grams hydrocarbon, Organic Material Hydrocarbon Equivalent, for alcohol

fuels, per gallon of fuel dispensed); (2) Federal preconditioning and sequencing provisions for integrated and non-integrated ORVR systems; and (3) Federal refueling steps common to both integrated and non-integrated ORVR systems.¹

Section 209(b) of the Act provides that, if certain criteria are met, the Administrator shall waive Federal preemption for California to enforce new motor vehicle emission standards and accompanying enforcement procedures. The criteria include consideration of whether California arbitrarily and capriciously determined that its standards are, in the aggregate, at least as protective of public health and welfare as the applicable Federal standards; whether California needs State standards to meet compelling and extraordinary conditions; and whether California's amendments are consistent with section 202(a) of the Act.

CARB determined that its ORVR standards and accompanying enforcement procedures do not cause California's standards, in the aggregate, to be less protective of public health and welfare than the applicable Federal standards. EPA received no comments that questioned CARB's determination. As indicated in footnote one, to the extent that CARB's ORVR regulation does not apply to gaseous fueled vehicles a waiver for such vehicles is not granted, and as further explained in the Decision Document the federal ORVR regulations apply to such vehicles. In all other respects EPA cannot make a finding that CARB's determination, that its ORVR requirements are, in the aggregate, at least as protective of public health and welfare, is arbitrary and capricious.

CARB has continually demonstrated the existence of compelling and extraordinary conditions justifying the need for its own motor vehicle pollution control program, which includes the subject standards and procedures. No

information has been submitted to demonstrate that California no longer has a compelling and extraordinary need for its own program. Therefore, I agree that California continues to have compelling and extraordinary conditions which require its own program, and, thus, I cannot deny the waiver on the basis of the lack of compelling and extraordinary conditions.

CARB has submitted information that the requirements of its emission standards and test procedures are technologically feasible and present no inconsistency with federal requirements and are, therefore, consistent with section 202(a) of the Act. No information has been presented to demonstrate that CARB's requirements are inconsistent with section 202(a) of the Act, nor does EPA have any other reason to believe that CARB's requirements are inconsistent with section 202(a). Thus, I cannot find that California's ORVR requirements will be inconsistent with section 202(a) of the Act. Accordingly, I hereby grant the waiver requested by California.

My decision will affect not only persons in California but also the manufacturers outside the State who must comply with California's requirements in order to produce motor vehicles for sale in California. For this reason, I hereby determine and find that this is a final action of national applicability.

Under section 307(b)(1) of the Act, judicial review of this final action may be sought only in the United States Court of Appeal for the District of Columbia Circuit. Petitions for review must be filed by October 21, 2002. Under section 307(b)(2) of the Act, judicial review of this final action may not be obtained in subsequent enforcement proceedings.

As with past waiver decisions, this action is not a rule as defined by Executive Order 12866. Therefore, it is exempt from review by the Office of Management and Budget as required for rules and regulations by Executive Order 12866.

In addition, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Finally, the Administrator has delegated the authority to make determinations regarding waivers of Federal preemption under section 209(b) of the Act to the Assistant Administrator for Air and Radiation.

Dated: August 13, 2002.

Robert Brenner,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 02-21290 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7263-5]

2002 Clean Air Excellence Awards Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency established the Clean Air Excellence Awards Program in February 2000. This is an annual awards program to recognize outstanding and innovative efforts that support progress in achieving clean air. This notice announces the competition for the Year 2002 program.

Awards Program Notice: Pursuant to 42 U.S.C. 7403(a)(1) and (2) and sections 103(a)(1) and (2) of the Clean Air Act (CAA), notice is hereby given that the EPA's Office of Air and Radiation (OAR) announces the opening of competition for the Year 2002 "Clean Air Excellence Awards Program" (CAEAP). The intent of the program is to recognize and honor outstanding, innovative efforts that help to make progress in achieving cleaner air. The CAEAP is open to both public and private entities. Entries are limited to the United States. There are six award categories: (1) Clean Air Technology; (2) Community Development/Redevelopment; (3) Education/Outreach; (4) Regulatory/Policy Innovations; (5) Transportation Efficiency Innovations; and (6) Outstanding Individual Achievement Award. Awards are recognition only and are given on an annual basis.

Entry Requirements and Deadline: All applicants are asked to submit their entry on a CAEAP entry form, contained in the CAEAP Entry Package, which may be obtained from the Clean Air Act Advisory Committee (CAAAC) web site at www.epa.gov/oar/caaac and click on Awards Program or by contacting Mr. Paul Rasmussen, U.S. EPA at 202-564-1306 or 202-564-1352 (Fax), mailing address: Office of Air and Radiation (6102A), 1200 Pennsylvania Avenue, NW., Washington, DC 20004. The entry form is a simple, three-part form asking for general information on the applicant and the proposed entry; asking for a description of why the entry is deserving of an award; and requiring

¹ Title 13, California Code of Regulations (CCR), section 1978 and the incorporated "California Refueling Emissions Standards and Test Procedures for 1998 and Subsequent Model Motor Vehicles" as adopted by CARB Executive Order G-96-026 on April 24, 1996. As explained below, EPA is not waiving section 1978 as it applies to vehicles fueled by CNG or LPG to the extent that CARB's ORVR regulation does not apply to such vehicles. In addition, EPA is not at this time waiving the amendments CARB made to section 1978 at its November 5, 1998 hearing including CARB's new regulation "California Refueling Emission Standards and Test Procedures for 2001 and Subsequent Motor Vehicles." EPA anticipated that it will consider CARB's new regulation and matters regarding CARB's clarifications on gaseous and gasoline fueled vehicles within the context of a future waiver proceeding or when California's regulations are brought within the scope of today's waiver.

information from three (3) independent references for the proposed entry. Applicants should also submit additional supporting documentation as necessary. Specific directions and information on filing an entry form are included in the Entry Package available through the directions above. The deadline for all submission of entries is September 19, 2002.

Judging and Award Criteria: Judging will be accomplished through a screening process conducted by EPA staff, with input from outside subject experts, as needed. A workgroup of the CAAAC will provide advice to EPA on the entries. The final award decision will be made by the EPA Assistant Administrator for Air and Radiation. Entries will be judged using both general criteria and criteria specific to each individual category. There are four (4) general criteria: (1) The entry directly or indirectly (i.e., by encouraging actions) reduces emissions of criteria pollutants or hazardous/toxic air pollutants; (2) The entry demonstrates innovation and uniqueness; (3) The entry provides a model for others to follow (i.e., it is replicable); and (4) The positive outcomes from the entry are continuing/sustainable. Although not required to win an award, the following general criteria will also be considered in the judging process: (1) The entry has positive effects on other environmental media in addition to air; (2) The entry demonstrates effective collaboration and partnerships; and (3) The individual or organization submitting the entry has effectively measured/evaluated the outcomes of the project, program, technology, etc. As mentioned above, additional criteria will be used for each individual award category. These criteria are listed in the 2002 Entry Package.

FOR FURTHER INFORMATION CONTACT: For further information concerning this new awards program please use the CAAAC Web site cited above or contact Paul Rasmussen at the telephone and address cited above.

Dated: August 8, 2002.

Robert Brenner,

Principal Deputy Assistant Administrator for Air and Radiation.

[FR Doc. 02-21289 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7264-2]

Assistance for Local Governments That Wish To Develop and Implement Environmental Management Systems (EMS)

AGENCY: Environmental Protection Agency.

ACTION: Notice; announcement of a program to assist local agencies that wish to voluntarily develop and implement environmental management systems (EMS); request for applications.

SUMMARY: The Environmental Protection Agency (EPA) announces its intention to assist up to ten local government organizations that wish to develop and implement environmental management systems (EMS). While no direct financial assistance would be provided to participants. Other assistance, in the form of training workshops, on-site visits, and electronic materials/consultation would be provided. EPA would provide partial funding for this program through a cooperative agreement with the Global Environment and Technology Foundation (GETF), a non-profit organization that specializes in EMS training and implementation, located in Annandale, Virginia, but the majority of the funding would be provided by the participants through individual agreements with GETF. GETF will then work closely with each participant throughout the life of the program and provide training, technical assistance, site visits, and other materials designed to help each participant develop a complete EMS, using the ISO 14001 International EMS Standard as a baseline. Participants would also be asked to communicate and share information with local stakeholders as their EMS is developed. Each participant would also provide data about their EMSs, including a short case study, to a National Clearinghouse of EMS Information that is designed to help a wide range of public agencies develop EMSs for their operations. This clearinghouse is located at www.peercenter.net.

This initiative is similar to and builds on the successes of two previous projects sponsored by EPA. More information on these projects can also be found at www.peercenter.net. The initiative is also consistent with EPA's overall policy position of encouraging EMS adoption in key sectors. This statement was recently signed by the EPA Administrator and can be found at www.epa.gov/ems.

This initiative is being led by EPA's Office of Water and co-sponsored by the Office of Air and Radiation and the Office of Solid Waste.

DATES: Letters of Application from interested organizations should be submitted no later than September 30, 2002.

ADDRESSES: Letters of application should be submitted in writing or faxed to: Craig Ruberti, Global Environment and Technology Foundation (GETF), 7010 Little River Turnpike, Suite 460, Annandale, Virginia, 22003, (703) 750-640, FAX (703) 750-6506.

FOR FURTHER INFORMATION CONTACT: Jim Horne, U.S. EPA, Office of Wastewater Management, 1200 Pennsylvania Avenue, NW., 20460, (202) 564-0571, horne.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Over the past 8-10 years, there has been increasing evidence that organizations that adopt environmental management systems (EMS) for their operations can realize significant benefits in terms of improved environmental performance, including but not limited to environmental compliance, prevention of pollution, increased operational efficiency, and improved relations with regulatory agencies. Originally adopted in the private sector, EMSs are now proving to be a powerful tool that can also help public agencies, especially local governments. EMSs do not impose new technical requirements, nor do they act as a substitute for existing regulatory requirements. EMSs provide a powerful and replicable method for an organization to more effectively manage its environmental obligations and, as a result, improve its overall environmental performance, including areas not subject to legal requirements. EMSs can also help organizations reduce unnecessary costs.

Since 1997, the U.S. Environmental Protection Agency (EPA) has led a major effort to assist and build partnerships with public agencies, primarily local governments, voluntarily adopt environmental management systems (EMS) for their operations, using the ISO 14001 International EMS Standard as a baseline. These initiatives have documented a series of important benefits for the 23 organizations that have participated including improved environmental performance, cost savings, and better community relations. The experiences of these agencies have also helped to demonstrate the value of EMSs in the public sector, provided much valuable information that can

help other public agencies in the future, and pointed out the need for EPA to continue to build strong partnerships with local governments that wish to adopt EMSs. Organizations interested in applying for the program described below are encouraged to learn more about the benefits that previous participants have realized through their EMSs by going to www.peercenter.net.

As a result of the successes of these efforts, EPA has recently launched the Public Entity EMS Resource Center Initiative (PEER). The PEER Initiative consists of two major components—(1) A national clearinghouse of EMS information geared to the particular needs of public agencies, especially local governments, located at www.peercenter.net and (2) a group of eight EMS Local Resource Centers (LRCs) around the country, housed in academic and other non-profit institutions, that can provide EMS assistance and training for public agencies in different areas around the country. A listing of these Local Resource Centers can be found at the Web site listed above. The national program described in this notice will compliment the work of the Local Resource Centers, help provide additional valuable for the information in the national clearinghouse described above, and maintain momentum for EMS adoption in the public sector.

II. Program Description

Participants in this program would be required to:

- (1) Develop an environmental management system (EMS) for an operation of their choosing, using the ISO 14001 International Standard as a baseline. Participants will be provided with information on the process, costs, and benefits of achieving 3rd party certification for their EMS, but will not be required to achieve certification;
- (2) Communicate and share information with local stakeholders as the EMS is developed;
- (3) Adopt performance objectives for the EMS that address compliance, environmental performance beyond compliance, and pollution prevention;
- (4) Share information about their EMS and other relevant information through the national clearinghouse of EMS information for public entities described above (www.peercenter.net).

The Global Environment and Technology Foundation (GETF), through a cooperative agreement with U.S. EPA, will work closely with each participant to help them meet these requirements, over a two year period beginning in late 2002. GETF will provide this assistance through regular

workshops involving all participants, site assistance visits for each participant, regular conference calls, and other written and electronic materials. In addition, participants will receive informal mentoring, as appropriate, from agencies that have participated in the two previous local government EMS initiatives sponsored by U.S. EPA.

III. Guidelines for Application

Organizations wishing to apply for this program need to:

1. Submit a letter of application to the person listed above in the summary of this Notice no later than September 30, 2002;
2. This letter should be signed by the head of the organization and contain the following information:

- A brief description of the organization and its responsibilities;
- The name of a top management representative who will have the responsibility and authority for ensuring that the EMS is developed based on the program description provided above. This person should be available to travel and participate in up to four workshops with other participants over the life of the project. These workshops will be held approximately every six months;
- A preliminary, non-binding indication of the particular operation for which the EMS will be developed (i.e. wastewater treatment plant, public works department, transit operation, etc.). If necessary, a final determination of the operation for which the EMS will be developed can take place once organizations have been selected for the program;
- A description of the reasons the organization wishes to participate in the program and some of the benefits it hopes to realize from adopting an EMS;
- Finally, a clear assurance that top management in the organization will provide the necessary visibility, staff time, and other resources necessary to successfully develop and implement the EMS through an EMS implementation team. Ongoing top management support is the most critical factor for ensuring a successful and sustainable EMS.

EPA funding will be provided through GETF and used to offset some of the costs of participating in the program, such as travel to workshops. However, participants will be asked to pay the majority of the costs of participation, through an agreement with GETF. This funding can be provided on a yearly basis. EPA believes the costs of

participation are competitive with costs incurred by other local governments to develop EMSs and that participation in this national program will provide significant benefits to each participant.

Once all applications are received, follow up interviews will be conducted by GETF with each applicant to discuss the information contained in their letter of application in more detail, along with any other information needed before final decisions on program participation are made. GETF will consult with EPA before final decisions are made. These final decisions are expected no later than November 20, 2002, after which GETF will work with each participant to schedule the first program workshop.

James A. Hanlon,

Director, Office of Wastewater Management.

[FR Doc. 02-21291 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7263-6]

Clean Air Act Advisory Committee Notice of Meeting

AGENCY: Environmental Protection Agency (EPA),

ACTION: Notice.

SUMMARY: The Environmental Protection Agency established the Clean Air Act Advisory Committee (CAAAC) on November 19, 1990, to provide independent advice and counsel to EPA on policy issues associated with implementation of the Clean Air Act of 1990. The Committee advises on economic, environmental, technical scientific, and enforcement policy issues.

Open Meeting Notice: Pursuant to 5 U.S.C. App.2 Section 10(a)(2), notice is hereby given that the Clean Air Act Advisory Committee will hold its next open meeting on Wednesday, October 30, 2002, from approximately 8:30 a.m. to 2:30 p.m. at the Renaissance Mayflower Hotel, 1127 Connecticut Ave., NW., Washington, DC. Seating will be available on a first come, first served basis. Three of the CAAAC's four Subcommittees (the Linking Energy, Land Use, Transportation, and Air Quality Concerns Subcommittee; the Permits/NSR/Toxics Integration Subcommittee; and the Economics Incentives and Regulatory Innovations Subcommittee) will hold meetings on Tuesday, October 29, 2002 from approximately 1 p.m. to 7 p.m. at the Renaissance Mayflower Hotel, the same location as the full Committee. The

Energy, Clean Air and Climate Change Subcommittee will not meet at this time. The schedule for the three Subcommittees meetings is: Linking Energy, Land Use, Transportation, and Air Quality—1 p.m. to 3 p.m.; Permits/NSR/Toxics—3 p.m. to 5 p.m.; and Economics Incentives and Regulatory Innovations—5 p.m. to 7 p.m.

Inspection of Committee Documents: The Committee agenda and any documents prepared for the meeting will be publicly available at the meeting. Thereafter, these documents, together with CAAAC meeting minutes, will be available by contacting the Office of Air and Radiation Docket and requesting information under docket item A-94-34 (CAAAC). The Docket office can be reached by telephoning 202-260-7548; FAX 202-260-4400.

FOR FURTHER INFORMATION CONTACT: For Further Information concerning this meeting of the full CAAAC, please contact Paul Rasmussen, Office of Air and Radiation, US EPA (202) 564-1306, FAX (202) 564-1352 or by mail at US EPA, Office of Air and Radiation (Mail code 6102 A), 1200 Pennsylvania Avenue, NW., Washington, DC 20004. For information on the subcommittee meetings, please contact the following individuals: (1) Permits/NSR/Toxics Integration—Debbie Stackhouse, 919-541-3554; and (2) Linking Transportation, Land Use and Air Quality Concerns—Robert Larson, 734-214-4277; and (3) Economic Incentives and Regulatory Innovations—Carey Fitzmaurice, 202-564-1667. Additional information on these meetings and for the CAAAC and its Subcommittees can be found on the CAAAC Web Site: www.epa.gov/oar/caaac/

Dated: August 8, 2002.

Robert D. Brenner,

Principal Deputy Assistant Administrator for Air and Radiation.

[FR Doc. 02-21288 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0207; FRL-7195-3]

Tribal Pesticide Programs Council; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Tribal Pesticide Program Council (TPPC), will hold a 2-day meeting, beginning on September 25, 2002, and ending on September 26, 2002. This notice announces the

location and times for the meeting and sets forth the tentative agenda topics.

DATES: The meeting will be held on September 25, 2002, from 9 a.m. to 5 p.m., and September 26, 2002, from 9 a.m. to 5 p.m. On September 25 and 26 at 1:15 to 2:15 p.m., the Tribal caucus is closed to EPA and the general public.

ADDRESSES: This meeting will be held at the Silver Star Hotel and Casino at Pearl River Resort, Highway 16 West, Choctaw, MS.

FOR FURTHER INFORMATION CONTACT: Georgia A. McDuffie, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 605-0195; fax number: (703) 308-1850; e-mail address: mcduffie.georgia@epa.gov.

Lillian Wilmore, Tribal Pesticide Program Council Facilitator, P.O. Box 470829; Brookline Village, MA 02447-0829; telephone number (617) 232-5742; fax number: (617) 277-1656; e-mail address: naecology@aol.com.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to Tribes with pesticide programs or pesticide interests. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0207. The official record consists of the documents specifically referenced in this action, any public comments

received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0207 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0/9.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0207. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Tentative Agenda

This unit provides tentative agenda topics for the 2-day meeting.

1. TPPC State of the Council Report.
2. Presentation and questions and answers by EPA's Office of Pesticide Programs, Field and External Affairs Division.
3. Reports from Working Groups and TPPC participation in other meetings:
 - Environmental indicators, Tribal Strategy and FOSTTA, Pesticide Program Dialogue Committee, Report on

the Western Regional Pesticide Conference, Certification and Training Advisory Group (CTAG), Water Quality and Pesticides Management, and Worker Protection.

4. Tribal caucus.
5. Reports from other Tribal organizations:
 - American Indian Environmental Office (AIEO), Tribal Operations Committee (TOC), Regional Tribal Operations Committee (RTOC), Intertribal Agricultural Council (IAC), and National Tribal Environmental Council (NTEC).
6. Homeland security.
7. Environmental Justice: Fish Consumption Report.
8. EPA's Office of Enforcement and Compliance Assurance (OECA) related issues.
 - i. Continuing issues reference.
 - ii. Data collections issues - Form 5700-33H.
9. Tribal caucus.
10. Section 18 and other Tribal authority issues.
11. Pesticide priorities for 2004 and 2005.
12. Updates from the Regional Offices.
13. EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) - Overview and subsistence issues focus.
14. Report on funding of special projects and water quality projects to Tribes and report from Blackfeet nation on their special project.
15. NAGPRA Working Group.
16. Federal Inspector credentials criteria.
17. Tribal code development: A panel discussion - with opportunity for questions.

List of Subjects

Environmental protection, Pesticide and pests.

Dated: August 12, 2002.

Anne E. Lindsay,

Director, Field and External Affairs, Office of Pesticide Programs.

FR Doc. 02-20994 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0159; FRL-7190-3]

Pronamide Tolerance Reassessment Decisions; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice of a tolerance reassessment for pronamide starts a 30-

day public comment period during which the public is encouraged to submit comments on the Agency's "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for pronamide." The Agency is providing an opportunity, through this notice, for interested parties to comment in accordance with procedures described in Unit I of this document. All comments will be carefully considered by the Agency. If any comment causes the Agency to revise its decision on reassessment of these tolerances, EPA will publish notice of its amendment in the **Federal Register**.

DATES: Comments, identified by docket control number OPP-2002-0159 must be received on or before September 20, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0159 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Cecelia Watson, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-4329; e-mail address: watson.cecelia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or the Federal Food, Drug, and Cosmetic Act (FFDCA); environmental, human health, and agricultural advocates; pesticides users; and members of the public interested in the use of pesticides. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the Federal Register listings at <http://www.epa.gov/fedrgstr/>.

To access TRED documents electronically, go directly to the TREDs table on the EPA Office of Pesticide Programs Home Page, at <http://www.epa.gov/pesticides/reregistration/status.htm>

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0159. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0159 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0/9.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0159. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the appropriate person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. What Action is the Agency Taking?

This notice constitutes and announces the availability of the TRED for pronamide. This decision has been developed as part of the public participation process that EPA and the U.S. Department of Agriculture (USDA) are using to involve the public in the reassessment of pesticide tolerances under FFDCA. EPA must review tolerances and tolerance exemptions that were in effect when FQPA was enacted in August 1996, to ensure that these existing pesticide residue limits for food and feed commodities meet the safety standard of the new law.

FFDCA requires EPA to review all the tolerances for registered chemicals in effect on or before the date of the enactment. In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a revocation occurs. A reregistration eligibility decision (RED) was completed for pronamide in April 1994, prior to FQPA enactment, and therefore needed an updated assessment to consider the provisions of the Act.

FFDCA requires that the Agency, when considering whether to establish, modify, or revoke a tolerance, consider "available information" concerning the cumulative effects of a particular pesticide's residue and "other substances that have a common mechanism of toxicity."

As indicated above, the Agency will also evaluate the cumulative risk, if necessary, posed by the entire group of chemicals with which a common mechanism of toxicity is shared, and issue a final tolerance reassessment decision once the cumulative

assessment for that group is completed. At this time, pronamide has not been identified as sharing a common method of toxicity and is not scheduled for a cumulative risk assessment.

All registrants of pesticide products containing one or more of the active ingredients listed in this document are being sent the TRED, and must respond to labeling requirements within 8 months of receipt. Furthermore, the Agency requests a response to all generic confirmatory data from technical registrants within 90 days of receipt.

The reregistration program is being conducted under congressionally-mandated time frames, and EPA recognizes both the need to make timely reregistration decisions and to involve the public. Therefore, EPA is issuing this TRED as a final document with a 30-day comment period. All comments will be carefully considered by the Agency. If any comment significantly affects the TRED, EPA will amend the TRED by publishing the amendment in the **Federal Register**.

B. What is the Agency's Authority for Taking this Action?

The legal authority for these TREDs falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, "the Administrator shall determine whether pesticides containing such active ingredients are eligible for reregistration," and either reregistering products or taking "other appropriate regulatory action."

List of Subjects

Environmental protection, Chemicals, Pesticides and pests, Tolerances.

Dated: August 2, 2002.

Lois A. Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 02-21295 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0186; FRL-7193-3]

Pesticide Product; Registration Approval

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of an application to register the pesticide product Bollgard II containing an active ingredient not

included in any previously registered product pursuant to the provisions of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT:

Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5412; e-mail address: cole.leonard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental

Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

To access a fact sheet which provides more detail on this registration, go to the Home Page for the Office of Pesticide Programs at <http://www.epa.gov/pesticides/>, and select "fact sheet."

2. *In person.* The Agency has established an official record for this action under docket control number OPP-2002-0186. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1221 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are also available for public inspection. Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 1200 Pennsylvania Ave., NW., Washington, DC 20460. The request should: Identify the product name and registration number and specify the data or information desired.

A paper copy of the fact sheet, which provides more detail on this registration, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

II. Did EPA Approve the Application?

The Agency approved the application after considering all required data on risks associated with the proposed use of Cry1Ac and Cry2Ab stacked proteins, and information on social, economic, and environmental benefits to be derived from use. Specifically, the

Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of Cry1Ac and Cry2Ab stacked proteins when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

III. Approved Applications

EPA issued a notice, published in the **Federal Register** of March 21, 2001 (66 FR 15867) (FRL-6770-6), which announced that Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO 63198, had submitted an application to register the pesticide product, Bollgard II Cotton (EPA File Symbol 524-LEE) containing the active *Bacillus thuringiensis* Cry2Ab protein and the genetic material necessary for its production (Vector GHBK11L) in cotton. Monsanto transformed a Bollgard cotton variety with vector GHBK11L using particle bombardment to add the Cry2Ab gene for full commercial registration on cotton. This product was not previously registered.

The application was approved on June 14, 2002, as Bollgard II, Plant-incorporated protectant containing Cry1Ac and Cry2Ab stacked proteins (EPA Registration Number 524-522) for a 20,000 acre seed increase.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: August 7, 2002.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 02-20873 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0208; FRL-7195-2]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain

pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2002-0208, must be received on or before September 20, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0208 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6224; e-mail address: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and

certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register—Environmental Documents.**" You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0208. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0208 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The

PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0208. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response.

You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests.

Dated: August 12, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Bayer Corporation

PP 0F6094

EPA has received a pesticide petition (0F6094) from Bayer Corporation, 8400 Hawthorn Road, Kansas City MO, 64120-0013, proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of propoxycarbazone-sodium, methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate, sodium salt and its metabolite, methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-(2'-hydroxy-propoxy)-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate in or on the raw agricultural commodities (RACs) wheat forage, wheat hay, wheat

straw, wheat grain, meat, and meat byproducts, (cattle, sheep, goats, horses, hogs), and milk at 1.5, 0.15, 0.05, 0.01, 0.05, and 0.002 parts per million (ppm); respectively. EPA has determined that the petition contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of MKH-6561 (propoxycarbazone-sodium) in wheat was rapid, as only minor amounts of MKH-6561 were found in some of the wheat matrices. The primary metabolic pathway in wheat appeared to be hydroxylation of the propoxy side chain of MKH-6561 to give Pr-2-OH MKH-6561 (methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-(2'-hydroxy-propoxy)-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate). Hydrolysis of Pr-2-OH MKH-6561 then gave Pr-2-OH NMT and, probably the sulfonamide methyl ester which was not observed in any wheat matrices. Hydrolysis of the sulfonamide methyl ester gave sulfonamide acid, which was in equilibrium with saccharin. A minor metabolic pathway was demethylation of MKH-6561 to yield *N*-desmethyl MKH-6561.

2. *Analytical method—i. Plant.* The proposed tolerance expression is MKH-6561 and Pr-2-OH MKH-6561. An analytical method was developed to measure these two analytes in plant matrices. The method was validated in wheat tissues. MKH-6561 and Pr-2-OH MKH-6561 were extracted from the wheat tissues with 0.05 M NH₄OH using accelerated solvent extraction. Trifluoroacetic acid (0.5 milliliter (mL)) and an isotopically labeled internal standard were added to the extract. The whole extract was loaded onto a C-18 solid phase extraction (SPE) cartridge. The C-18 SPE cartridge was washed with aqueous trifluoroacetic acid (0.1%) and aqueous acetic acid (0.1%). A three to one mixture of acetonitrile and aqueous acetic acid (0.1%) was used to elute the analytes from the C-18 SPE cartridge. Water and acetic acid were added to the sample which was analyzed by LC/MS/MS.

ii. *Animal.* The proposed tolerance expression is MKH-6561. An analytical method was developed to measure this analyte in animal tissues and milk. The method was validated in animal tissues and milk. MKH-6561 was extracted from the tissues with 0.05 M NH₄OH

using accelerated solvent extraction. Trifluoroacetic acid (0.5 mL) and an isotopically labeled internal standard were added to the extract which was then centrifuged at 2,000 rpm for 10 minutes. Approximately half of the sample was loaded onto a C-18 SPE cartridge. The C-18 SPE cartridge was washed with aqueous trifluoroacetic acid (0.1%) and aqueous acetic acid (0.1%). A three to one mixture of acetonitrile and aqueous acetic acid (0.1%) was used to elute the analytes from the C-18 SPE cartridge. Water and acetic acid were added to the sample which was analyzed by LC/MS/MS. Milk samples were analyzed by amending an aliquot of milk with trifluoroacetic acid (0.5 mL) and isotopically labeled internal standard. The sample was purified by C-18 SPE as described above. The resultant sample was analyzed by LC/MS/MS.

3. *Magnitude of residues.* Twenty-one field trials were conducted in 19 locations to evaluate the quantity of MKH-6561 and Pr-2-OH MKH-6561 in wheat forage, hay, straw, and grain following treatment with MKH-6561, 70 water dispersible granule (WG) at an application rate of 45 grams of active ingredient per hectare in the spring or at 30 grams active ingredient per hectare in the fall and 30 grams active ingredient per hectare in the spring. The highest average field trial (HAFT) residue in wheat forage, hay, straw, and grain were 1.21, 0.12, 0.03, and <0.01 ppm respectively.

B. Toxicological Profile

1. *Acute toxicity.* i. MKH-6561 is of very low acute toxicity to fasted rats following a single oral administration. The acute oral LD₅₀ is >5,000 milligrams/kilogram/body weight (mg/kg bwt) for males and females.

ii. MKH-6561 is not toxic to rats following a single dermal application. The acute dermal LD₅₀ is >5,000 mg/kg bwt for males and females.

iii. An acute inhalation study with rats showed low toxicity with a 4-hour dust aerosol LC₅₀ 5,030 mg/m³ air for males and females.

iv. An eye irritation study in rabbits showed minimal irritation completely reversible within 48 hours.

v. A dermal irritation study in rabbits showed slight irritation completely reversible within 48 hours.

vi. MKH-6561 has no skin sensitizing potential under the conditions of the maximization test in guinea pigs.

2. *Genotoxicity.* The genotoxic action of MKH-6561 was studied in bacteria and mammalian cells with the aid of various *in vitro* test systems (*Salmonella* microsome test, hypoxanthine guanine

phosphoribosyl transferase (HGPRT) test with chinese hamster V79 cells, cytogenetic study with chinese hamster V79 cells, and unscheduled DNA synthesis (UDS) test) and in one *in vivo* test (micronucleus test). None of the tests revealed any evidence of a mutagenic or genotoxic potential of MKH-6561. The compound did not induce point mutation, DNA damage or chromosome aberration (CA).

3. *Reproductive and developmental toxicity.* i. In a 2-generation reproduction study, Wistar rats were administered MKH-6561 at levels of 0, 1,000, 4,000, or 16,000 ppm in the diet. The no observe adverse effect level (NOAEL) for reproductive parameters was established at 16,000 ppm (1,231 mg/kg bwt/day in males and 1,605 mg/kg bwt/day in females), the highest dose tested (HDT). The parental NOAEL was 1,000 ppm (80 mg/kg bwt/day in F₁ males and 93 mg/kg bwt/day in F₀ females).

ii. A developmental toxicity study was conducted with Wistar rats via oral gavage of MKH-6561 at levels of 0, 100, 300, and 1,000 mg/kg bwt/day on days 6 through 19 of gestation. There were no signs of maternal toxicity, embryotoxicity, fetotoxicity, or teratogenicity at the level of 1,000 mg/kg bwt/day. Therefore, the maternal and developmental NOAELs for rats were established at 1,000 mg/kg bwt/day, the limit dose for this study type. No teratogenic potential of MKH-6561 was evident in rats.

iii. Himalayan rabbits were administered MKH-6561 at levels of 0, 20, 100, 500, or 1,000 mg/kg bwt/day by oral gavage on days 6 through 28 post coitum in a test for developmental toxicity. A maternal NOAEL of 100 mg/kg bwt/day was established based on cold ears, alopecia, swelling of vulva, decreased feed, and water intake, body weight loss, gastrointestinal tract (GI) effects, liver effects, and thyroid hormone level effects. The gestation rate NOAEL of 100 mg/kg bwt/day was based on one abortion (assessed as secondary due to maternal toxicity) at 500 mg/kg bwt/day. The NOAEL for fetal parameters of 500 mg/kg bwt/day was based on placental effects, increased post-implantation loss, decreased number of fetuses, decreased fetal weight, retarded fetal skeletal ossification, and possible increase in lobulation of liver in fetuses at 1,000 mg/kg bwt/day. No teratogenic potential of MKH-6561 was evident in rabbits.

4. *Subchronic toxicity.* i. A 28-day dermal toxicity study in Wistar rats established a local and systemic NOAEL of 1,000 mg/kg bwt/day (the dermal limit dose) for males and females.

ii. A 14-week feeding study was conducted with Wistar rats at dietary dose levels of 0, 250, 1,000, 4,000, or 20,000 ppm. The NOAEL was determined to be 4,000 ppm (286.4 mg/kg bwt/day in males and 350.6 mg/kg bwt/day in females) based upon increased water consumption (reversible during the 4-week recovery period) and an irritative effect of the forestomach epithelium (reversible during the 4-week recovery period) in males and females dosed at 20,000 ppm as well as reduced glucose and triglyceride levels in females only dosed at 20,000 ppm.

iii. A 91-day feeding study was conducted with B6C3F₁ mice at dietary dose levels of 0, 625, 2,500, or 10,000 ppm. The NOAELs determined for males and females were 625 ppm (205 mg/kg bwt/day) and 2,500 ppm (1,159 mg/kg bwt/day), respectively, based on decreased body weights in 2,500 ppm males and 10,000 ppm females.

iv. A 2-month range-finding feeding study in Beagle dogs, at levels of 0, 1,000, 5,000, 10,000, and 40,000 ppm in the diet established a NOAEL of 10,000 ppm (322.2 mg/kg bwt/day in males and 285.6 mg/kg bwt/day in females) based on elevated hepatic biotransformation enzymes at 40,000 ppm.

5. *Chronic toxicity.* i. A 2-year chronic/oncogenicity study was conducted with male and female Fischer 344 rats at dietary levels of 0, 50, 500, or 1,000 mg/kg bwt/day for approximately the first 7 months of the study (dose adjustment). From approximately 7 months to study termination, the doses were 0, 1,000, 10,000, and 20,000 ppm in the diet. A chronic toxicity NOAEL of 1,000 ppm (43 mg/kg bwt/day in males and 49 mg/kg bwt/day in females) was determined based on increased urine pH and decreased body weight gain at 1-year (but not 2 years) at 10,000 ppm and 20,000 ppm. No carcinogenic potential was indicated.

ii. B6C3F₁ mice were administered MKH-6561 via the diet at levels of 0, 280, 1,400, and 7,000 ppm in a 2-year chronic feeding/carcinogenicity study. The chronic toxicity NOAEL was established at 1,400 ppm (369.0 mg/kg/day in males and 626.9 mg/kg bwt/day in females) based on retarded body weight development. No carcinogenic potential was indicated.

iii. A 1-year feeding study in Beagle dogs was conducted at 0, 2,000, 10,000, and 25,000 ppm in the diet. The NOAEL in males was determined to be 10,000 ppm (258.0 mg/kg bwt/day) based upon increased absolute adrenal gland weight without an increase in relative adrenal gland weight and slight enlargement of

zona fasciculata microscopically, without a correlation to adrenal gland weight in males dosed at 25,000 ppm. The NOAEL in females was determined to be 2,000 ppm (55.7 mg/kg bwt/day) based upon decreased food consumption and decreased relative heart weight in females dosed at 10,000 and 25,000 ppm.

6. *Animal metabolism.* i. A single oral dose of 2 mg/kg/bwt [triazolinone-3-¹⁴C]MKH-6561 was administered to rats. Between 22% and 24% of the administered dose was absorbed. Maximum plasma radiation levels were observed 0.33 hours after dosing. Within 48 hours of dosing, between CA 88% and 97% of the radioactivity was excreted via urine and feces. Approximately 80–88% of the excreted radioactivity was unchanged parent compound. The highest single metabolite concentration was CA 3% of the administered dose. The terminal elimination half-life for total radioactivity was CA 12–13 hours, so no bioaccumulation of MKH-6561 or its metabolites will occur.

ii. Single oral doses of 2 mg/kg/bwt and 200 mg/kg/bwt [phenyl-UL-¹⁴C]MKH-6561 were administered to rats. Between CA 21–31% of the administered dose was absorbed. Maximum plasma radiation levels were observed after 0.33 hours (low dose) and 1-hour (high dose). Within 48 hours of dosing, CA 97–104% of the administered dose was eliminated via urine and feces. Approximately 75–86% of the administered dose was eliminated as unchanged parent compound. The maximum single metabolite concentration was 8.8% of the administered dose. At the end of the study, less than 0.25% of the administered dose was found in organs and tissues. In a separate bile fistulation experiment, the predominantly fecal elimination was confirmed to be due to incomplete absorption of radioactivity from the GI tract. The terminal elimination half-life for total radioactivity was CA 9–11 hours, so no bioaccumulation of MKH-6561 or its metabolites will occur.

iii. Laying hens were given a daily dose of protonated MKH-6561 [phenyl-UL-¹⁴C] at 3.12 mg/kg/bwt for 3 consecutive days. The residue levels were 1.343 ppm in liver, 0.017 ppm in muscle, 0.014 ppm in fat, 0.006 ppm in the day-1 eggs, 0.009 ppm in the day-2 eggs, and 0.012 ppm in the day-3 eggs. The residue levels based on a theoretical 1x application rate, as determined from residue levels observed in the MKH-6561 wheat field trials would all be considerably less than 0.001 ppm. The major residue

identified in tissues and eggs were MKH-6561, Pr-2-OH MKH-6561, MKH-6561 sulfonamide methyl ester, and saccharin. The major metabolic pathway of MKH-6561 [phenyl-UL-¹⁴C] in poultry was hydrolysis of the parent compound producing *N*-methyl propyl triazolinone and sulfonamide methyl ester. The sulfonamide methyl ester was then converted to saccharin. A minor pathway involved hydroxylation at the 2-position of the triazolinone propoxy group. In the liver, the major metabolic pathway led to the formation of protein bound MKH-6561 residue through conjugation with the amino acid serine.

iv. Laying hens were given a daily dose of protonated MKH-6561 [triazolinone-3-¹⁴C] at 2.91 mg/kg/bwt for 3 consecutive days. The residue levels were 0.184 ppm in liver, 0.044 ppm in muscle, 0.015 ppm in the fat, 0.011 ppm in the day-1 egg, 0.016 ppm in the day-2 egg, and 0.022 ppm in the day-3 egg. The residue levels in tissues and eggs based on a theoretical 1x application, as determined from the residue levels observed in the MKH-6561 wheat field trials, would all be considerably less than 0.001 ppm. The metabolism of MKH-6561 [triazolinone-3-¹⁴C] appeared to involve both hydroxylation at the 2-position of the propoxy group and hydrolysis of the phenyl sulfonamide linkage.

v. Goats were dosed with 1.0 mg/kg/bwt of MKH-6561 [phenyl-UL-¹⁴C] for 3 consecutive days. Residue levels were 3.643 ppm in liver, 0.486 ppm in kidney, 0.009 ppm in muscle, 0.004 ppm in fat, 0.015 ppm in day-1 milk and, 0.022 ppm in day-2 milk. The metabolic pathway was based on hydrolysis of the sulfonamide to yield MKH-6561 sulfonamide methyl ester and saccharin. The saccharin was then conjugated to proteins which were found mainly in the liver and kidney.

vi. Goats were dosed with MKH-6561 [triazolinone-3-¹⁴C] at a dose of 0.98 mg/kg/bwt for 3 consecutive days. Residue levels were 0.171 ppm in liver, 0.425 ppm in kidney, 0.040 ppm in muscle, 0.007 ppm in fat, 0.046 ppm in day-1 milk, and 0.057 ppm in day-2 milk. The metabolism of MKH-6561 involved the cleavage of the phenyl sulfonylurea side chain and the hydroxylation of the propyl side chain on the triazolinone ring system after the cleavage of the phenyl sulfonylurea side chain.

7. *Metabolite toxicology.* i. 4-OH-saccharin is of low acute toxicity to fasted rats following a single oral administration. The acute oral LD₅₀ is >5,000 mg/kg/bwt for males and females. 4-OH-saccharin is considered non-mutagenic with and without S9 mix in the plate incorporation as well as in

the preincubation modification of the *Salmonella* microsome test.

ii. MKH-8394 is of very low acute toxicity to fasted rats following a single oral administration. The acute oral LD₅₀ is >5,000 mg/kg/bwt for males and females. MKH-8394 is considered non-mutagenic with and without S9 mix in the plate incorporation as well as in the preincubation modification of the *Salmonella* microsome test.

iii. KTS-9061 (Pr-2-OH MKH-6561) is not toxic to fasted rats following a single oral administration. The acute oral LD₅₀ is >5,000 mg/kg/bwt for males and females. KTS-9061 is considered non-mutagenic with and without S9 mix in the plate incorporation as well as in the preincubation modification of the *Salmonella*/microsome test. KTS-9061 is considered non-clastogenic with and without S9 mix CA test *in vitro* using chinese hamster V79 cells. Wistar rats were administered KTS-9061 via the diet at levels of 0, 800, 4,000, and 10,000 ppm for approximately 4 weeks. The NOAEL was determined to be 10,000 ppm (905.3 mg/kg bwt/day in males and 880.0 mg/kg bwt/day in females), the HDT.

iv. KTS-9304 has low to moderate acute toxicity to fasted rats following a single oral administration. The acute oral LD₅₀ was 263 mg/kg/bwt in males and 1,756 mg/kg/bwt in females. KTS-9304 is considered non-mutagenic with and without S9 mix in the plate incorporation as well as in the preincubation modification of the *Salmonella*/microsome test.

8. *Endocrine disruption.* There is no evidence to suggest that MKH-6561 has an effect on the endocrine system. Studies in this data base include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short-term and long-term exposure. These studies revealed no endocrine effects due to MKH-6561.

9. *Other studies.* i. An acute neurotoxicity screening study in Wistar rats established a NOAEL for males and females of 2,000 mg/kg/bwt (HDT).

ii. A 13-week neurotoxicity screening study in Wistar rats established a NOAEL of 20,000 ppm (1,321 mg/kg bwt/day in males and 1,651 mg/kg/day in females) (HDT). No neurotoxic potential was observed..

iii. A Plaque-Forming-Cell Assay to investigate immunotoxicological potential was performed on male Wistar rats after an approximate 4-week exposure of 0, 4,000, 10,000, or 20,000 ppm in the diet. The Plaque-Forming-Cell Assay NOAEL was 20,000 ppm (2,144 mg/kg bwt/day; HDT). The

overall study NOAEL was 10,000 ppm (986 mg/kg bwt/day) based upon increased water intake at 20,000 ppm.

C. Aggregate Exposure

1. Dietary exposure—i. Food.

Estimates of chronic dietary exposure to residues of MKH-6561 utilized the proposed tolerances in wheat forage, wheat hay, wheat straw, wheat grain, meat, and meat byproducts (cattle, sheep, goats, horses, hogs), and milk of 1.5, 0.15, 0.05, 0.01, 0.05, and 0.002 ppm respectively. Other assumptions were that 100% of the target crop would be treated with MKH-6561 and that no loss of residue would occur due to processing or cooking. For chronic exposures, a reference dose (RfD) of 0.43 mg/kg/day was assumed based on and NOAEL of 43 mg/kg bwt/day from the combined chronic toxicity/oncogenicity study in the rat. A safety factor of 100 was used based on interspecies extrapolation (10x) and intraspecies variability (10x). Using these conservative assumptions, dietary residues of MKH-6561 contribute 0.000219 mg/kg/day (0.1% of the RfD) for children 1 to 6 years old, the most sensitive sub-population. For the U.S. population, the exposure was 0.000098 mg/kg/day (0.02% of the RfD). For acute dietary exposure, the same conservative assumptions were made. A NOAEL of 100 mg/kg bwt/day from the developmental toxicity study in rabbits and an safety factor of 100 were used in the acute dietary assessment. The safety factor of 100 was based on interspecies extrapolation (10x) and intraspecies variability (10x). Acute dietary exposure at the 95th percentile was negligible for all population subgroups. For children 1 to 6 years old (the most sensitive sub-population,) and for the U.S. population, <0.1% of the acute RfD was consumed at the 95th percentile.

ii. *Drinking water.* Estimates of chronic dietary exposure to residues of MKH-6561 utilized the proposed tolerances in wheat forage, wheat hay, wheat straw, wheat grain, meat, and meat byproducts (cattle, sheep, goats, horses, hogs), and milk of 1.5, 0.15, 0.05, 0.01, 0.05, and 0.002 ppm respectively. Other assumptions were that 100% of the target crop would be treated with MKH-6561 and that no loss of residue would occur due to processing or cooking. For chronic exposures, an RfD of 0.43 mg/kg/day was assumed based on and NOAEL of 43 mg/kg bwt/day from the combined chronic toxicity/oncogenicity study in the rat. A safety factor of 100 was used based on interspecies extrapolation (10x) and intraspecies variability (10x). Using these conservative assumptions,

dietary residues of MKH-6561 contribute 0.000219 mg/kg/day (0.1% of the RfD) for children 1 to 6 years old, the most sensitive sub-population. For the U.S. population, the exposure was 0.000098 mg/kg/day (0.02% of the RfD). For acute dietary exposure, the same conservative assumptions were made. A NOAEL of 100 mg/kg bwt/day from the developmental toxicity study in rabbits and an safety factor of 100 were used in the acute dietary assessment. The safety factor of 100 was based on interspecies extrapolation (10x) and intraspecies variability (10x). Acute dietary exposure at the 95th percentile was negligible for all population subgroups. For children 1 to 6 years old (the most sensitive sub-population,) and for the U.S. population, <0.1% of the acute RfD was consumed at the 95th percentile.

2. *Non-dietary exposure.* There are no current non-food uses for BAY MKH-6561 registered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. No non-food uses are proposed for BAY MKH6561 and no non-dietary exposures are expected for the general population.

D. Cumulative Effects

BAY MKH-6561 is a sulfonamide herbicide. There is no information to suggest that any chemical in this class of herbicides has a common mechanism of mammalian toxicity or that chemicals in this class produce similar effects so it is not appropriate to combine exposures of BAY MKH-6561 with other herbicides. Bayer Corporation is considering only the potential risk of BAY MKH-6561.

E. Safety Determination

1. *U.S. population.* As presented previously, the exposure of the U.S. general population to MKH-6561 is low, and the risks, based on comparisons to the RfD, are minimal. The margins of safety from the use of MKH-6561 are well within EPA's acceptable limits. Bayer Corporation concludes that there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposure to MKH-6561 residues.

2. *Infants and children.* The complete toxicological data base including the developmental toxicity and 2-generation reproduction studies were considered in assessing the potential for additional sensitivity of infants and children to residues of BAY MKH-6561. The developmental toxicity studies in rats and rabbits revealed no increased sensitivity of rats or rabbits to *in-utero* exposure to BAY MKH-6561. The 2-generation reproduction study did not reveal any increased sensitivity of rats

to *in-utero* or postnatal exposure to BAY MKH-6561. Furthermore, none of the other toxicology studies revealed any data demonstrating that young animals were more sensitive to BAY MKH-6561 than adult animals. The data taken collectively clearly demonstrate that application of a FQPA uncertainty factor for increased sensitivity of infants and children is not necessary for BAY MKH-6561.

F. International Tolerances

There are currently no international Codex tolerances established for BAY MKH-6561. It is not currently registered in any other countries. There are no harmonized maximum residue levels at the European Union level at present.

[FR Doc. 02-21294 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0172 FRL-7191-1]

Notice of Filing of Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2002-0172, must be received on or before September 20, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0172 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
.....	112	Animal production
.....	311	Food manufacturing
.....	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0172. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any

information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0172 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticides Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0172. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA to response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with

procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that the petitions contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 14, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner summary of the pesticide petitions is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petitions were prepared by the Interregional Research Project No. 4 (IR-4) and represents the view the Interregional Research Project No. 4 EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project No. 4 (IR-4)

PP 0E6178, 2E6386, 2E6410, and 2E6432

EPA has received pesticide petitions (0E6178, 2E6386, 2E6410, and 2E6432) from the Interregional Research Project No. 4 (IR-4), Rutgers, The State University of New Jersey, Highway No. 1 South, North Brunswick, NJ, 08902-3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.493 by establishing tolerances for residues of the fungicide dimethomorph [(E,Z)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]-morpholine] in or on the following raw agricultural commodities: Dried cone hop at 60 parts per million (ppm) (0E6178); leaf lettuce and head lettuce at 10 ppm (2E6386); cucurbit vegetable group at 0.5 ppm (2E6410); and bulb vegetable group at 2 ppm (2E6432). A related petition (PP 8F4946) for the establishment of a tolerance for residues of dimethomorph in or on imported dried hops cones at 45 ppm has previously been filed by American Cyanamid Company. This notice includes summaries of the petitions prepared by BASF Corporation, Research Triangle Park, NC. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of these petitions. Additional data may be needed before EPA rules on these petitions.

A. Residue Chemistry

1. *Plant metabolism.* The nature of the residues of dimethomorph is adequately understood. No metabolites were identified that require regulation.

2. *Analytical method.* A reliable method for the determination of dimethomorph residues in dried hops cones, lettuce (head and leaf), cucurbit vegetables (crop group 9), and bulb vegetables (crop group 3) exists; this method is the FDA Multi-Residue Method, Protocol D, as published in the Pesticide Analytical Manual 1.

3. *Magnitude of residues.* Complete residue data for dimethomorph and the petitioned tolerances have been submitted. The data support the requested tolerances.

B. Toxicological Profile

1. *Acute toxicity*—i. An acute oral toxicity study was conducted in the Sprague-Dawley rat for dimethomorph technical with a lethal dose (LD)₅₀ of 4,300 milligrams/kilogram body weight (mg/kg bwt) for males and 3,500 mg/kg bwt for females. Based upon EPA toxicity criteria, the acute oral toxicity category for dimethomorph technical is Category III or slightly toxic.

ii. Oral LD₅₀ studies were conducted on the two isomers (E and Z) alone:

a. An acute oral toxicity study in the wistar rat for the E-isomer with a LD₅₀ greater than 5,000 mg/kg bwt for males and approximately 5,000 mg/kg bwt for females.

b. An acute oral toxicity study in the wistar rat for the Z-isomer with a LD₅₀ greater than 5,000 mg/kg bwt for both males and females.

iii. An acute dermal toxicity study was conducted in the Wistar rat for dimethomorph technical with a dermal LD₅₀ greater than 5,000 mg/kg bwt for both males and females. Based on the EPA toxicity category criteria, the acute dermal toxicity category for dimethomorph is Category IV or relatively non-toxic.

iv. A 4-hour inhalation study was conducted in wistar rats for dimethomorph technical with a lethal concentration (LC)₅₀ greater than 4.2 mg/L for both males and females. Based on the EPA toxicity category criteria, the acute inhalation toxicity category for dimethomorph technical is Category IV or relatively non-toxic.

2. *Genotoxicity*—i. Salmonella reverse gene mutation assays (2 studies) were negative up to a limit dose of 5,000 grams (g)/plate. Chinese hamster lung V79 cells were negative up to toxic doses in two studies.

ii. Two chinese hamster lung structural chromosomal studies were

reportedly positive for chromosomal aberrations at the highest dose tested (HDT) (160 grams milliliter (g/mL)/-S9; 170 g/mL/+S9). Dimethomorph induced only a weak response in increasing chromosome aberrations in this test system. These results were not confirmed in two micronucleus tests under in vivo conditions.

iii. Structural chromosomal aberration studies were weakly positive in human lymphocytic cultures, but only in S9 activated cultures treated at 422 g/mL, the HDT, were strongly cytotoxic. No increase in chromosomal aberrations was observed in the absence of S9 activation at all doses. Furthermore, the positive clastogenic response observed under the in vitro conditions was not conformed in two in vivo micronucleus assays.

iv. Micronucleus assay (2 studies) indicated that dimethomorph was negative for inducing micronuclei in bone marrow cells of mice following intraperitoneal administration of doses up to 200 mg/kg or oral doses up to the limit dose of 5,000 mg/kg. Thus, dimethomorph was found to be negative in these studies for causing cytogenic damage in vivo.

v. Dimethomorph was negative for inducing unscheduled DNA synthesis, in cultured rat liver cells, at doses up to 250 g/mL, a weakly cytotoxic level.

vi. Dimethomorph was negative for transformation in Syrian hamster embryo cells treated, in the presence and absence of activation, up to cytotoxic concentrations (265 g/mL/+S9; 50 g/mL/-S9).

3. *Reproductive and developmental toxicity*—i. A rat developmental toxicity study was conducted with the lowest observed adverse effect level (LOAEL) for maternal toxicity of 160 mg/kg/day and the no observed adverse effect level (NOAEL) for maternal toxicity of 60 mg/kg/day. The NOAEL for developmental toxicity is 60 mg/kg/day. Dimethomorph is not carcinogenic in the Sprague-Dawley rat.

ii. A rabbit development toxicity study was conducted with a LOAEL for maternal toxicity of 650 mg/kg/day and a NOAEL for maternal toxicity of 300 mg/kg/day. The NOAEL for developmental toxicity is 650 mg/kg/day, the HDT.

iii. A two-generation rat reproduction study was conducted with a LOAEL for parental systemic toxicity of 1,000 ppm, or approximately 80 mg/kg/day, and a NOAEL for parental systemic toxicity of 300 ppm, or approximately 24 mg/kg/day. The NOAEL for fertility and reproductive function was 1,000 ppm, the highest concentration tested (HCT), or approximately 80 mg/kg bwt/day.

4. *Subchronic toxicity*—i. A 90-day dietary study was conducted in Sprague-Dawley rats with a NOAEL of greater than or equal to 1,000 ppm, the HCT, or approximately 73 mg/kg/day for males and 82 mg/kg/day for females.

ii. A 90-day dog dietary study was conducted with a NOAEL of 450 ppm, or approximately 15 mg/kg/day, and a LOAEL of 1,350 ppm, or approximately 43 mg/kg/day.

5. *Chronic toxicity*—i. A 2-year chronic toxicity study was conducted in Sprague-Dawley rats with a NOAEL of 200 ppm or approximately 9 mg/kg/day for males and 12 mg/kg/day for females. The LOAEL for systemic toxicity is 750 ppm, or approximately 36 mg/kg/day for males and 58 mg/kg/day for females.

ii. A 1-year chronic toxicity study was conducted in dogs with a NOAEL of 450 ppm, or approximately 14.7 mg/kg/day and a LOAEL of 1,350, or approximately 44.6 mg/kg/day.

iii. A 2-year carcinogenicity study was conducted in Sprague-Dawley rats with a NOAEL for systemic toxicity of 200 ppm, or approximately 9 mg/kg/day for males and 11 mg/kg/day for females. The LOAEL for systemic toxicity was 750 ppm, or approximately 34 mg/kg/day for males and 46 mg/kg/day for females. There was no evidence of increased incidence of neoplastic lesions in treated animals. The NOAEL for carcinogenicity is 2,000 ppm, the HCT, or approximately 95 mg/kg/day for males and 132 mg/kg/day for females.

iv. A 2-year carcinogenicity study was conducted in mice with a NOAEL for systemic toxicity of 100 mg/kg/day and a LOAEL of 1,000 mg/kg/day. There was no evidence of increased incidence of neoplastic lesions in treated animals. The NOAEL for carcinogenicity is 1,000 mg/kg/day, the HDT.

6. *Animal metabolism*. Results from the livestock and rat metabolism studies show that orally administered dimethomorph was rapidly excreted by the animals. The principal route of elimination is the feces.

7. *Metabolite toxicology*. There were no metabolites identified in plant or animal commodities which require regulation.

8. *Endocrine disruption*. Collective organ weights and histopathological findings from the two-generation reproduction study in rats, as well as from the subchronic and chronic toxicity studies in two or more animal species, demonstrate no apparent estrogenic effects or effects on the endocrine system. There is no information available which suggests that dimethomorph technical would be associated with endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*. Tolerances have been established (40 CFR 180.493) for the residues of dimethomorph in or on potatoes at 0.05 ppm, potatoes, wet peel at 0.15 ppm, tomato at 0.5 ppm, tomato paste at 1.0 ppm, hop, dried cones at 60 ppm (import tolerance) and time-limited tolerances have been established for cantaloupe, cucumber, squash and watermelon at 1 ppm and on the cereal grains group: fodder at 0.15 ppm, forage and grain at 0.05 ppm, hay at 0.10 ppm, and straw at 0.15 ppm.

i. *Food*—a. *Acute dietary exposure*. An acute dietary risk assessment is not required because no acute toxicological endpoints were identified by EPA for dimethomorph.

b. *Chronic dietary exposure*. To assess the potential chronic dietary exposure to dimethomorph residues for all tolerances in effect early in 1999, EPA used the Dietary Exposure Evaluation Model (DEEM®) to conduct a chronic dietary (food only) exposure analysis. In conducting this analysis, EPA made very conservative assumptions: That all commodities having dimethomorph tolerances contain residues of dimethomorph and that those residues are at the level of the tolerance. These assumptions result in an overestimate of human dietary exposure. All section 18 tolerances (cantaloupe, watermelon, cucumber, squash, and tomato) were included in this assessment along with tolerances for cereal grain crops and potato.

ii. *Drinking water*. The Generic Estimated Environmental Concentration (GENEEC) was 24 parts per billion (ppb) for 56 days. This model was used to determine surface water residues. Dimethomorph residues in ground water were also estimated using the Screening Concentration in Ground Water (SCI-GROW) model, but these estimates were significantly lower than those obtained from the GENEEC model. Given the low levels of dimethomorph residues as estimated by the GENEEC model, the additional use of dimethomorph on hops, lettuce, cucurbit vegetables, and bulb vegetables is not expected to reach a level of concern for residues in drinking water.

2. *Non-dietary exposure*. Currently, there are no registered residential uses for dimethomorph in the United States. Thus, an assessment of non-dietary exposure is not relevant to this petition.

D. Cumulative Effects

There is no information to indicate that any toxic effects produced by dimethomorph would be cumulative with those of any other chemical. The

fungicidal mode of action of dimethomorph is unique; dimethomorph inhibits cell wall formation only in Oomycete fungi. The result is lysis of the cell wall that kills growing cells and inhibits spore formation in mature hyphae. This unique mode of action and limited pest spectrum suggest that there is little or no potential for cumulative toxic effects in mammals. In addition, the toxicity studies submitted to support this petition do not indicate that dimethomorph is a particularly toxic compound. No toxic end-points of potential concern were identified.

E. Safety Determination

1. *U.S. population*. The cPAD is 0.1 mg/kg bwt/day, based on a NOAEL of approximately 10 mg/kg bwt/day (200 ppm) from a 2-year dietary toxicity study in rats that demonstrated decreased body weight and liver foci in females at 750 ppm. The cPAD is calculated using an uncertainty factor of 100. The theoretical maximum residue contribution (TMRC) for lettuce, cucurbit and bulb vegetable is estimated at 0.003 mg/kg bwt/day for the general population. This represents a dietary exposure to the general population of the United States that is 3.0% of the cPAD. The TMRC for dried hops cones is estimated at 0.0000515 mg/kg bwt/day for the general population. This represents a dietary exposure to the general population of the United States which is 0.05% of the cPAD. The combined TMRC for all current and pending dimethomorph tolerances in potato, tomato, grape, hop, cereal grain commodities, lettuce (head and leaf), endive (escarole), radicchio, cucurbit vegetable (crop group 9), and bulb vegetable (crop group 3) will utilize less than 10% of the cPAD for the general U.S. population. Since EPA generally has no concern for exposures below 100% of the cPAD, there is a reasonable certainty that no harm will result from aggregate exposure to dimethomorph residues in or on commodities of the cited crops.

Drinking Water

i. *Lettuce, cucurbit and bulb vegetables*. Currently, the only federally registered food/feed uses of dimethomorph in the United States are on potato and tomato crops. For these uses, the Drinking Water Level of Concern (DWLOC) from chronic exposure to dimethomorph was estimated by BASF to be 2,800 ppb for the U.S. population and for males 13 years and older, and 910 ppb for children 1–6 years of age. Given the low levels of dimethomorph residues as

estimated by the GENEEC model, the large margin of exposure (38x-116x), and the similar use patterns of dimethomorph on commodities of the cited crops, the additional proposed uses of dimethomorph are not expected to reach a level of concern for residues in drinking water.

ii. *Hops*. For this use, the DWLOC from chronic exposure to dimethomorph was estimated by EPA to be 3,400 ppb for the U.S. population and for males 13 years and older, 2,900 ppb for females 13 years and older, and 960 ppb for children (1–6 years of age). Given the low levels of dimethomorph residues as estimated by the GENEEC model and the large margin of exposure (40x-142x), the additional use of dimethomorph on hops is not expected to reach a level of concern for residues in drinking water.

2. *Infants and children*. The TMRC for all commodities covered in this petition is minimal. The consumption of residues of dimethomorph on lettuce (head and leaf), cucurbit vegetables (crop group 9), and bulb vegetables (crop group 3) will use approximately 7.0% of the cPAD for children ages 1–6. The TMRC for residues of dimethomorph in hops as consumed by infants, non-nursing infants, children ages 1–6, and children ages 7–12 are each estimated to be 0.00% of the cPAD. Moreover, the combined TMRC values for all current and pending dimethomorph tolerances will utilize less than 10% of the cPAD for each of the subgroups.

The results of the studies submitted to support this package provide no evidence that dimethomorph caused reproductive, developmental or reproductive effects. No such effects were noted at dose levels that were not maternally toxic. The NOAELs observed in the developmental and reproductive studies were 6 to 65 times higher than the NOAEL used to establish the cPAD. There is no evidence to indicate that children or infants would be more sensitive than adults to toxic effects caused by exposure to dimethomorph.

Therefore, the registrant believes that the results of the toxicology and metabolism studies support both the safety of dimethomorph to humans based on the intended use as a fungicide on domestically produced hops, lettuce (head and leaf), cucurbit vegetables (crop group 9), and bulb vegetables (crop group 3) and the granting of the requested tolerances.

F. International Tolerances

There are no Canadian, Mexican, or codex MRLs established for dimethomorph for the commodities

associated with this request; consequently, a discussion of international harmonization is not relevant.

[FR Doc. 02–21279 Filed 8–16–02; 4:19 pm]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0170; FRL–7190–9]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0170, must be received on or before September 20, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0170 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing

Categories	NAICS codes	Examples of potentially affected entities
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0170. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m.,

Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

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1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
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II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

August 15, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the Interregional

Research Project Number 4 (IR-4), and represents the view of IR-4. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 (IR-4)

PP 2E6404

EPA has received a pesticide petition 2E6404 from Interregional Research Project Number 4 (IR-4), 681 US Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.473 by establishing a tolerance for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolite, 3-methylphosphinopropionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid in or on the raw agricultural commodities blueberry, lingonberry, junberry, and salal at 0.10 part per million (ppm). This notice includes a summary of the petition prepared by Aventis CropScience U.S.A., P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The nature of residues found in plants as a result of a treatment of glufosinate-ammonium is well understood.

2. *Analytical method.* The enforcement analytical method utilizes gas chromatography for detecting and measuring levels of glufosinate-ammonium and metabolites with a general limit of quantification of 0.05 ppm. This method allows detection of residues at or above the proposed tolerances.

3. *Magnitude of residues.* Field residue trials were conducted at sites in New Jersey, New Hampshire, North Carolina, and Michigan. The treatment regime was selected to represent the use

pattern that is the most likely to result in the highest residues. Glufosinate-ammonium derived residues did not exceed 0.072 ppm in blueberries when sampled at 14 days or more after the last treatment.

B. Toxicological Profile

1. *Acute toxicity.* Glufosinate-ammonium has been classified as toxicity category III for acute oral, dermal, and inhalation toxicity and for eye irritation. Glufosinate-ammonium is not a dermal irritant (toxicity category IV) nor is it a dermal sensitizer. The oral lethal dose (LD)₅₀ is 2 grams/kilogram (g/kg) in male rats and 1.62 g/kg in female rats.

2. *Genotoxicity.* Based on results of a complete genotoxicity data base, there is no evidence of mutagenic activity in a battery of studies, including: *Salmonella* spp., *E. coli*, *in vitro* mammalian cell gene mutation assays, mammalian cell chromosome aberration assays, *in vivo* mouse bone marrow micronucleus assays, and unscheduled DNA synthesis assays.

3. *Reproductive and developmental toxicity.* In a developmental toxicity study, groups of 20 pregnant female Wistar rats were administered glufosinate-ammonium by gavage at doses of 0, 0.5, 2.24, 10, 50, and 250 milligrams/kilogram/day (mg/kg/day) from days 7 to 16 of pregnancy. The no observed adverse effect level (NOAEL) for maternal toxicity is 10 mg/kg/day; the LOAEL is 50 mg/kg/day based on vaginal bleeding and hyperactivity in dams. In the fetus, the NOAEL is 50 mg/kg/day, based on dilated renal pelvis observations at the lowest observed adverse effect level (LOAEL) of 250 mg/kg/day.

In a developmental toxicity study, groups of 15 pregnant female Himalayan rabbits were administered glufosinate-ammonium by gavage at doses of 0, 2.0, 6.3, or 20.0 mg/kg/day from days 7 to 19 of pregnancy. In maternal animals, decreases in food consumption and body weight gain were observed at the 20 mg/kg/day dose level. The NOAEL for maternal toxicity was 6.3 mg/kg/day and that for developmental toxicity was 20 mg/kg/day.

In a multi-generation reproduction study, glufosinate-ammonium was administered to groups of 30 male and 30 female Wistar/Han rats in the diet at concentrations of 0, 40, 120, or 360 ppm. The LOAEL for systemic toxicity is 120 ppm based on increased kidney weights in both sexes and generations. The systemic toxicity NOAEL is 40 ppm. The LOAEL for reproductive/developmental toxicity is 360 ppm based on a decreased number of viable

pups at this dose. The NOAEL is 120 ppm.

4. *Subchronic toxicity.* In a subchronic oral toxicity study, glufosinate-ammonium was administered to 10 NMRI mice/sex/dose in the diet at levels of 0, 80, 320, or 1,280 ppm (equivalent to 0, 12, 48 or 192 mg/kg/day for 13 weeks. Significant ($p < 0.05$) increases were observed in serum aspartate aminotransferase and in alkaline phosphatase in high-dose (192 mg/kg/day) males. Also observed were increases in absolute and relative liver weights in mid-(48 mg/kg/day) and high-dose males. The NOAEL is 12 mg/kg/day, the LOAEL is 48 mg/kg/day based on the changes in clinical biochemistry and liver weights.

5. *Chronic toxicity.* In a combined chronic toxicity/carcinogenicity study, glufosinate-ammonium was administered to 50 Wistar rats/sex/dose in the diet for 130 weeks at dose levels of 0, 40, 140, or 500 ppm (mean compound intake in males was 0, 1.9, 6.8, and 24.4 mg/kg/day and for females was 0, 2.4, 8.2, and 28.7 mg/kg/day, respectively). A dose-related increase in mortality was noted in females at 140 and 500 ppm; whereas in males, increased absolute and relative kidney weights were noted at 140 ppm and 500 ppm. The NOAEL was considered to be 40 ppm. No treatment-related carcinogenic response was noted.

In a carcinogenicity study, glufosinate-ammonium was administered to 50 NMRI mice/sex/dose in the diet at dose levels of 0, 80, 160 (males only), or 320 (females only) ppm for 104 weeks. The NOAEL for systemic toxicity is 80 ppm (10.82/16.19 mg/kg/day in males/females (M/F), and the LOAEL is 160/320 ppm (22.60/ 63.96 mg/kg/day in M/F), based on increased mortality in males, increased glucose levels in males and females, and changes in glutathione levels in males. No increase in tumor incidence was found in any treatment group.

In a chronic feeding study, technical glufosinate-ammonium was fed to male and female beagle dogs for 12 months in the diet at levels of 2.0, 5.0, or 8.5 mg/kg/day. The NOAEL is 5.0 mg/kg/day based on clinical signs of toxicity, reduced weight gain and mortality at the 8.5 mg/kg/day dose level. In a rat carcinogenicity study, glufosinate-ammonium was administered to Wistar rats (60/sex/group) for up to 24 months at 0, 1,000, 5,000, or 10,000 ppm (equivalent to 0, 45.4, 228.9, or 466.3 mg/kg/day in males and 0, 57.1, 281.5, or 579.3 mg/kg/day in females). The LOAEL for chronic toxicity is 5,000 ppm (equivalent to 228.9 mg/kg/day for male rats and 281.5 mg/kg/day for

females), based on increased incidences of retinal atrophy. The chronic NOAEL is 1,000 ppm. Under the conditions of this study, there was no evidence of carcinogenic potential. Dosing was considered adequate based on the increased incidence of retinal atrophy.

6. *Animal metabolism.* Studies conducted in rats using ¹⁴C-glufosinate-ammonium have shown that the compound is poorly absorbed (5-10%) after oral administration and is rapidly eliminated primarily as the parent compound. The highest residue levels were found in liver and kidney tissues.

The metabolic profile and the quantitative distribution of metabolites were very similar in both goat and hen. The vast majority of the dose was excreted, primarily as parent compound. The very limited residues found in edible tissues, milk and eggs were comprised principally of glufosinate and 3-methylphosphinopropionic acid (Hoe 061517), with lesser amounts of N-acetyl-L-glufosinate (Hoe 099730) and 2-methylphosphinopropionic acid (Hoe 064619).

7. *Metabolite toxicology.* Additional testing has been conducted with the major metabolites, 3-methylphosphinopropionic acid, and N-acetyl-L-glufosinate. Based on subchronic and developmental toxicity study results, a profile of similar or less toxicity was observed for the metabolites as compared to the parent compound, glufosinate-ammonium.

8. *Endocrine disruption.* No special studies have been conducted to investigate the potential of glufosinate-ammonium to induce estrogenic or other endocrine effects. However, no evidence of estrogenic or other endocrine effects have been noted in any of the toxicology studies that have been conducted with this product and there is no reason to suspect that any such effects would be likely.

C. Aggregate Exposure

1. *Dietary exposure.* Tolerances have been established (40 CFR 180.473) for the combined residues of glufosinate-ammonium and metabolites in or on a variety of raw agricultural commodities. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicity studies. EPA has, therefore, not established an acute reference dose (RfD) for the general population including infants and children. An acute RfD of 0.063 mg/kg/day was established, however, for the females 13+ subgroup. Therefore, an acute dietary analysis was conducted for this subpopulation; whereas, chronic dietary

analysis was conducted for the usual populations.

i. *Food.* An acute dietary analysis was conducted using the Dietary Exposure Evaluation Model™ (DEEM) software and the 1994–1996 CSFII consumption data base. The analysis assumed tolerance level residues for all commodities and 100% of crop treated for all registered or pending uses. This tier one analysis resulted in an exposure of 0.007552 mg/kg bwt/day (95th percentile) for the female 13+ subpopulation (the only population of concern) representing 36% utilization of the acute reference dose (RfD).

Chronic dietary analysis was conducted to estimate exposure to potential glufosinate-ammonium residues in or on registered and proposed commodities. The DEEM software and the 1994–1996 USDA food consumption data were used. Tolerance level residues were assumed for all commodities. Percent crop treated values generated by the agency were incorporated as follows: Tree nuts 1%; apples, 1%; field corn, 2.6%; grapes, 1%; and soybeans, 1%. Aventis CropScience estimates that an upper bound value for cotton at market maturity is 20% and that for potato is 10%. All other crops are included at 100% of crop treated. Chronic dietary exposure estimates from residues of glufosinate-ammonium for the U.S. population represented approximately 25% of the chronic RfD; whereas that for children 1–6, the subpopulation with the highest exposure, represented approximately 61% of the chronic RfD. This analysis was based on highly conservative assumptions, yet still indicates that dietary exposures for all segments of the population are well within the chronic RfDs. The Agency has no concerns with RfD utilization up to 100%.

ii. *Drinking water.* EPA's standard operating procedure for Drinking Water Exposure and Risk Assessments was used to perform the drinking water assessment. The models Screening Concentration in Ground Water (SCI-GROW) and EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM-EXAMS) were used to estimate the concentration of glufosinate-ammonium that might occur in water. The acute drinking water level of comparison (DWLOC) for females 13+ is 403 parts per billion (ppb). In comparison, the acute drinking water estimated concentrations (DWELOC) calculated by the Generic Expected Environmental Concentration (GENEEC) is 127 ppb.

The chronic DWLOC calculated for adults is 185 ppb and that for children/

toddlers is 41 ppb. The chronic DWELOC calculated using a worst case scenario is 31 ppb (GENEEC). The DWLOCs are based on highly conservative dietary (food) exposures and are expected to be much higher in real world situations reducing further the percent utilization of the DWLOC.

2. *Non-dietary exposure.* Glufosinate-ammonium is currently registered for use on the following non-food sites: areas around ornamentals, shade trees, Christmas trees, shrubs, walks, driveways, flower beds, farmstead buildings, in shelter belts, and along fences. It is also registered for use as a post-emergent herbicide on farmsteads, areas associated with airports, commercial plants, storage and lumber yards, highways, educational facilities, fence lines, ditch banks, dry ditches, schools, parking lots, tank farms, pumping stations, parks, utility rights-of-way, roadsides, railroads, and other public areas and similar industrial and non-food crop areas. It is also registered for lawn renovation uses.

EPA has determined that there are no acute or chronic non-dietary exposure scenarios. Further, the Agency has determined that it is not appropriate to aggregate short- and intermediate-term non-dietary exposure with dietary exposures in risk assessments because the end-points are different.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has indicated that, at this time, the Agency does not have available data to determine whether glufosinate-ammonium has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, glufosinate-ammonium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance petition, therefore, it has not been assumed that glufosinate-ammonium has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above and based on the completeness and reliability of the toxicity data, it is concluded that chronic dietary exposure

to the registered and proposed uses of glufosinate-ammonium will utilize at most 25% of the chronic RfD for the U.S. population. The actual exposure is likely to be significantly less than predicted by this analysis as data and models that are more realistic are developed. Exposures below 100% of the RfD are generally assumed to be of no concern because the RfD dose represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health.

The acute population of concern, female 13+ utilizes 36% of the acute RfD. This is a tier one highly conservative assessment and actual exposure is likely to be far less. DWLOCs based on dietary exposures are greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food, drinking water and nonresidential) to residues of glufosinate-ammonium and metabolites.

2. *Infants and children.* The toxicological data base is sufficient for evaluating prenatal and postnatal toxicity for glufosinate-ammonium. There are no prenatal or postnatal susceptibility concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproduction study. Based on clinical signs of neurological toxicity in short and intermediate dermal toxicity studies with rats, EPA has determined that an added FQPA safety factor of 3x is appropriate of assessing the risk of glufosinate-ammonium derived residues in crop commodities. Using the conservative assumptions described in the exposure section above, the percent of the chronic reference dose that will be used for exposure to residues of glufosinate-ammonium in food for children 1–6 years old (the most highly exposed subgroup) is 61%. Infants utilize 37% of the chronic RfD. As in the adult situation, DWLOCs are higher than the worst case drinking water estimated concentrations and are expected to use well below 100% of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of glufosinate-ammonium.

F. International Tolerances

The codex maximum residue limit for glufosinate-ammonium and metabolite in or on berries and other small fruits (except for currants) has been

established by the Codex Alimentarius Commission at 0.10 ppm.

[FR Doc. 02-21280 Filed 8-16-02; 4:19 pm]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0177; FRL-7191-6]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2002-0177, must be received on or before September 20, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0177 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0177. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is

imperative that you identify docket ID number OPP-2002-0177 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0177. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 13, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for

the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1E6321, 2E6354, 2E6370, 2E6384, 2E6400, and 2E6422

EPA has received pesticide petitions (1E6321, 2E6354, 2E6370, 2E6384, 2E6400, and 2E6422) from IR-4 New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.495 by establishing tolerances for residues of spinosad, Spinosyn A (Factor A; CAS#131929-60-7) or 2-[(6-deoxy-2,3,4-tri-O-methyl- α -L-mannopyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H- as Indaceno [3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS# 131929-63-0) or 2-[(6-deoxy-2,3,4-tri-O-methyl- α -L-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9, 10,11,12,13,14,16a, 16b-tetradecahydro-4,14-methyl-1H- as Indaceno [3,2-d]oxacyclododecin-7,15-dione in or on the following raw agricultural commodities: fig at 0.1 parts per million (ppm) (1E6321), herbs subgroup at 8.0 ppm (2E6354), root vegetable subgroup at 0.1 (2E6384), dry bulb onion at 0.1 ppm (2E6384), caneberry subgroup at 0.7 ppm (2E6400), grape at 0.6 ppm (2E6422), raisin at 0.6 ppm (2E6422), grape juice at 1.2 ppm (2E6422), and peanut at 0.02 ppm (2E6370).

This notice includes a summary of the petitions prepared by Dow Agro Sciences LLC, Indianapolis, IN 46268. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on these petitions.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of spinosad in plants (apples, cabbage, cotton, tomato, and turnip) is adequately understood for the purposes of these tolerances. A rotational crop study showed no carryover of measurable spinosad related residues in representative test crops.

2. *Analytical method.* There is a practical method (immunoassay) for detecting (0.005 ppm) and measuring (0.01 ppm) levels of spinosad in or on food with a limit of detection that allows monitoring of food with residues at or above the level set for these tolerances. The method has had a successful method tryout in the EPA's laboratories.

3. *Magnitude of residues.* The magnitude of residues for spinosad is adequately understood for the purpose of the proposed tolerances.

B. Toxicological Profile

1. *Acute toxicity.* Spinosad has low acute toxicity. The rat oral lethal dose (LD)₅₀ is 3,738 milligrams/kilograms (mg/kg) for males and <5,000 mg/kg for females, whereas the mouse oral lethal dose (LD)₅₀ is <5,000 mg/kg. The rabbit dermal LD₅₀ is <5,000 mg/kg and the rat inhalation lethal concentration (LC)₅₀ is <5.18 mg/l air. In addition, spinosad is not a skin sensitizer in guinea pigs and does not produce significant dermal or ocular irritation in rabbits. End use formulations of spinosad that are water based suspension concentrates have similar low acute toxicity profiles.

2. *Genotoxicity.* Short term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vitro* assay for cytogenetic damage using the Chinese hamster ovary cells, an *in vitro* mammalian gene mutation assay using mouse lymphoma cells, an *in vitro* assay for DNA damage and repair in rat hypothecates, and an *in vivo* cytogenetic assay in the mouse bone marrow (micro nucleus test) have been conducted with spinosad. These studies show a lack of genotoxicity.

3. *Reproductive and developmental toxicity.* Spinosad caused decreased body weights in maternal rats given 200 mg/kg/day by gavage highest dose tested (HDT). This was not accompanied by either embryo toxicity, fetal toxicity, or developmental. The no observed adverse effect level (NOAEL) for maternal and fetal toxicity in rats were 50 and 200 mg/kg/day, respectively. A developmental study in rabbits showed that spinosad caused decreased body weight gain and a few abortions in maternal rabbits given 50 mg/kg/day (HDT). Maternal toxicity was not accompanied by either embryo toxicity, fetal toxicity, or developmental. The NOAEL for maternal and fetal toxicity in rabbits were 10 and 50 mg/kg/day, respectively. In a 2-generation reproduction study in rats, parental toxicity was observed in both males and females given 100 mg/kg/day (HDT). Perinatal effects (decreased litter size and pup weight) at 100 mg/kg/day were

attributed to maternal toxicity. The NOAEL for maternal and pup effects was 10 mg/kg/day.

4. *Subchronic toxicity.* Spinosad was evaluated in 13-week dietary studies and showed a NOAEL of 4.89 and 5.38 mg/kg/day, respectively in male and female dogs; 6 and 8 mg/kg/day, respectively in male and female mice; and 33.9 and 38.8 mg/kg/day, respectively in male and female rats. No dermal irritation or systemic toxicity occurred in a 21-day repeated dose dermal toxicity study in rabbits given 1,000 mg/kg/day.

5. *Chronic toxicity.* Based on chronic testing with spinosad in the dog and the rat, the EPA has set a reference dose (RfD) of 0.027 mg/kg/day for spinosad. The RfD has incorporated a 100-fold safety factor to the NOAEL found in the chronic dog study to account for inter- and intra-species variation. The NOAEL shown in the dog chronic study was 2.68 and 2.72 mg/kg/day, respectively for male and female dogs. The NOAEL (systemic) shown in the rat chronic/carcinogenicity/neurotoxicity study were 9.5 and 12.0 mg/kg/day, respectively for male and female rats.

Using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), it is proposed that spinosad be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in 2 species. There was no evidence of carcinogenicity in an 18-month mouse feeding study and a 24-month rat feeding study at all dosages tested. The NOAEL shown in the mouse carcinogenicity study was 11.4 and 13.8 mg/kg/day, respectively for male and female mice. A maximum tolerated dose was achieved at the top dosage level tested in both of these studies based on excessive mortality. Thus, the doses tested are adequate for identifying a cancer risk. Accordingly, a cancer risk assessment is not needed.

6. *Animal metabolism.* There were no major differences in the bioavailability, routes or rates of excretion, or metabolism of spinosyn A and spinosyn D following oral administration in rats. Urine and fecal excretions were almost completed in 48-hours post-dosing. In addition, the routes and rates of excretion were not affected by repeated administration.

7. *Metabolite toxicology.* The residue of concern for tolerance setting purposes is the parent material (spinosyn A and spinosyn D). Thus, there is no need to address metabolite toxicity.

8. *Endocrine disruption.* There is no evidence to suggest that spinosad has an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary exposure—i. Food.* For purposes of assessing the potential dietary exposure from use of spinosad on the raw agricultural commodities listed in this notice as well as from other existing spinosad crop uses, a conservative estimate of aggregate exposure is determined by basing the theoretical maximum residue contribution (TMRC) on the proposed tolerance level for spinosad and assuming that 100% of these proposed new crops and other existing (registered for use) crops grown in the U.S. were treated with spinosad. The TMRC is obtained by multiplying the tolerance residue levels by the consumption data which estimates the amount of crops and related foodstuffs consumed by various population subgroups. The use of a tolerance level and 100% of crop treated clearly results in an overestimate of human exposure and a safety determination for the use of spinosad on crops cited in this summary that is based on a conservative exposure assessment.

ii. *Drinking water.* Another potential source of dietary exposure are residues in drinking water. Based on the available environmental studies conducted with spinosad wherein it's properties show little or no mobility in soil, there is no anticipated exposure to residues of spinosad in drinking water. In addition, there is no established maximum concentration level for residues of spinosad in drinking water.

2. *Non-dietary exposure.* Spinosad is currently registered for outdoor use on turf and ornamentals at low rates of application (0.04 to 0.54 lb active ingredient (a.i.) per acre) and indoor use for drywood termite control (extremely low application rates used with no occupant exposure expected). Thus, the potential for non-dietary exposure to the general population is considered negligible.

D. Cumulative Effects

The potential for cumulative effects of spinosad and other substances that have a common mechanism of toxicity is also considered. In terms of insect control, spinosad causes excitation of the insect nervous system, leading to involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism that is clearly novel and unique among known insecticidal compounds. Spinosad also has effects on the GABA receptor function that may contribute further to its insecticidal activity. Based on results found in tests

with various mammalian species, spinosad appears to have a mechanism of toxicity like that of many amphiphilic cationic compounds. There is no reliable information to indicate that toxic effects produced by spinosad would be cumulative with those of any other pesticide chemical. Thus it is appropriate to consider only the potential risks of spinosad in an aggregate exposure assessment.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions and the RfD, the aggregate exposure to spinosad use on existing crop uses utilizes 40.5% of the RfD for the U.S. population from a previous EPA assessment based on the chronic population adjusted dose (cPAD). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The new crop uses proposed in this notice are minor ones and are expected to contribute only a negligible impact to the RfD. Thus, it is clear that there is reasonable certainty that no harm will result from aggregate exposure to spinosad residues on existing and all pending crop uses listed in this notice.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of spinosad, data from developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of pups.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the data base for spinosad relative to pre- and post-natal effects for children is complete. Further, for spinosad, the NOAEL in the dog chronic feeding study which was used to calculate the RfD (0.027 mg/kg/day) is already lower than the NOAEL from the developmental studies in rats and rabbits by a factor of more than 10-fold.

Concerning the reproduction study in rats, the pup effects shown at the HDT were attributed to maternal toxicity. Therefore, it is concluded that an additional uncertainty factor is not needed and that the RfD at 0.027 mg/kg/day is appropriate for assessing risk to infants and children.

In addition, the 10X factor to account for enhanced sensitivity of infants and children is not needed because: (1) The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or post-natal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and 2-generation reproduction in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity, (2) no neurotoxic signs have been observed in any of the standard required studies conducted, (3) the toxicology data base is complete and there are no data gaps, and (4) exposure data are complete or are estimated based on data that reasonably account for potential exposure.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent RfD utilized by the aggregate exposure to residues of spinosad on existing crop uses is 84.4% for children 1 to 6 years old, the most sensitive population subgroup from an EPA assessment based on the chronic population adjusted dose (cPAD). The new crop uses proposed in this notice are minor ones and are expected to contribute only a negligible impact to the RfD. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on the above proposed uses including existing crop uses.

F. International Tolerances

There are no Codex maximum residue levels (MRLs) established for residues of spinosad on grapes, herbs, caneberries, root vegetables, dry bulb onions, or figs. [FR Doc. 02-21281 Filed 8-16-02; 4:19 pm]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0184; FRL-7194-7]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2002-0184, must be received on or before September 20, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0184 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8380; e-mail address: gandhi.bipin@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register—Environmental Documents**." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0184. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0184 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs

(OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0184. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

August 12, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Magna Bon Corporation

2E6476

EPA has received a pesticide petition (2E6476) from Magna Bon Corporation,

1531 NW 25th Drive, Okeechobee, FL 34972 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by amending an established exemption from the requirement of a tolerance for sulfuric acid in 40 CFR 180.1001(c). Currently this tolerance exemption allows the use of sulfuric acid as an inert ingredient for pre-harvest and post-harvest uses with a limitation of 0.1% in the pesticide formulation when used as a pH control agent. This petition proposes to increase the limitation to 10% and to include a new use as a chelating agent. This petition also requests the establishment of an exemption from the requirement of a tolerance in plants and plants products, meat, milk, poultry, eggs, fish, shellfish, and irrigated crops when it results from the use of sulfuric acid as an inert ingredient in a pesticide product used in irrigation conveyance systems and lakes, ponds, reservoirs, or bodies of water in which fish or shellfish are cultivated.

EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* Sulfuric acid is used to adjust the pH in water in mix tanks and will be continually used for other purposes, such as chelation, etc. In-can formulations also use sulfuric acid for the same reasons. The metabolism of sulfuric acid is well known in the literature (see Reregistration Eligibility Decision (RED)) FACTS, December 1993 - an EPA RED Fact Sheet which is available through EPA's pesticide website (<http://www.epa.gov/pesticides>). Sulfuric acid is already registered as an active ingredient (10%) on garlic and onion when used as an herbicide and for the purpose of defoliation of crop plants such as potatoes. The metabolism of sulfuric acid was examined at the time of reregistration. Sulfuric acid is also used as a sanitizer for food processing and dairy facilities, and equipment and utensils used in food and feed contact.

The current exemption from the requirement of a tolerance in 40 CFR 180.1001(c) describing the limitation for sulfuric acid as an inert in the "formulated product" should be changed to read 10% rather than the exemption from a tolerance at the level

of 0.1%. Any data in the existing files can be used to support this change in the "formulated" product. The use pattern should be changed from use only as a pH control agent to "a chelating agent." People may be exposed to sulfuric acid in the formulated product. However this exposure involves such dilute solutions when in the "final use dilution" applied that it is believed inconsequential.

The product will also be applied post-harvest and the sulfuric acid in a formulation will not affect the metabolism of harvested products. Sulfuric acid is already used to sanitize milk lines and food processing surfaces by wipe-on and CIP treatments. The use as an inert in formulations in the "final use dilution" will not increase risk when used in formulations applied to growing crops or to raw agricultural commodities after harvest, meat, milk, poultry, eggs, fish, shellfish, and irrigated crops. In addition, sulfuric acid can be used in formulations as an algaecide, herbicide, or fungicide in irrigation conveyance systems and lakes, ponds, reservoirs, or bodies of water which fish or shellfish are cultivated or the bodies of water to be used for drinking water.

2. *Analytical method.* Standard methodology for sulfuric acid is adequate.

3. *Magnitude of residues.* The sulfuric acid will be used in accordance with good agricultural practices and no residues are expected. The history of the compound suggests that the product is safe for use on or in products for uses on/in plants, animals, humans and potable water.

Sulfuric acid will be applied as an inert ingredient according to labels approved by the EPA at rates reflected in a change in the wording of the tolerance exemption that reads 0.1% to 10.0%. The "final use dilution" will contain considerably less sulfuric acid when applied to growing crops, post-harvest produce, drinking water, meat, milk, poultry, eggs, fish, shellfish, irrigated crops, conveyance systems, lakes, ponds, reservoirs, or bodies of water in which fish or shellfish are cultivated or water that is used for drinking water. Since the product is not systemic the product can be washed from the surface of the plant or animal parts before being consumed as the normal practice.

B. Toxicological Profile

1. *Acute toxicity.* The toxicology of sulfuric acid is well-known. The toxicology file for registrations which use sulfuric acids as an active ingredient are available through EPA's data bases.

In addition, EPA has issued a RED document: Mineral Acids, in 1994, which includes sulfuric acid. This document explored the toxicology profile of sulfuric acid. The website is: <http://www.epa.gov/pesticides/reregistration/status.htm>.

The literature is full of references on the acute toxic effects of sulfuric acid. The data file for Magna Bon includes a toxicology study performed with sulfuric acid used as an inert at 4%. A material safety data sheet is available upon request.

2. *Genotoxicity.* There is no known genotoxicity. All studies have been negative.

3. *Reproductive and developmental toxicity.* There are no known effects on man or other animals.

4. *Subchronic toxicity.* There are no known effects on man or other animals.

5. *Chronic toxicity.* There are no known effects on man or other animals.

6. *Animal metabolism.* There are no known adverse effects to animals.

7. *Metabolite toxicology.* The metabolism of sulfuric acid is well known.

8. *Endocrine disruption.* There are no known effects on man.

C. Aggregate Exposure

1. *Dietary exposure.* Sulfuric acid is present in small amounts in every day living. Sulfur dioxide is present in air as the result of petro-chemical combustion. Sulfuric acid is formed as a result of the combination of water and sulfur dioxide in the air and is common in all metropolitan areas.

Sulfuric acid being used as a crop protector or in a post-harvest application will add little exposure given the current exposure.

Although there are no guideline studies for this data requirement *per se*, there is adequate information in the extensive open literature on sulfuric acid to characterize its toxicity.

In addition, sulfuric acid is Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration.

i. *Food.* The total consumption of agricultural products, fish, shell-fish, and meat treated with sulfuric acid can be calculated as being at or below daily minimums of mineral requirements for humans. In addition, the plant and meat products are washed before cooking.

ii. *Drinking water.* A food additive tolerance is requested in potable water at a level of 0.1 ppm maximum.

2. *Non-dietary exposure.* The population is exposed to sulfuric acid on an almost daily basis. Dermal exposure is the most prevalent.

D. Cumulative Effects

There are no cumulative effects. The amount of sulfuric acid used to treat the plants, harvested plant products, fish, shellfish, poultry, and meat would be a way of lowering bacterial, fungi and even-viral organisms from becoming a problem under most circumstances.

E. Safety Determination

1. *U.S. population.* Using sulfuric acid will reduce costs of protecting the above-mentioned products and giving adequate protection to such post-harvested crops, fish, shellfish, poultry, and meat products without harm to humans, animals, plants, plant products and the environment.

2. *Infants and children.* Foods are washed and processed. Sulfuric acid food products will be washed. The foods are normally further processed with the result of little or no detectable levels of sulfuric acid.

F. International Tolerances

The countries of the world have not restricted sulfuric acid for the purposes requested.

[FR Doc. 02-21296 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7265-3]

Real-Time Monitoring for Toxicity Caused by Harmful Algal Blooms and Other Water Quality Perturbations; Correction

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability; correction.

SUMMARY: On August 14, 2002, the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) of the Office of Research and Development (ORD) published a notice in the **Federal Register** (67 FR 53001) announcing the availability of a final report titled, *Real-Time Monitoring for Toxicity Caused by Harmful Algal Blooms and Other Water Quality Perturbations* (EPA/600/R-01/103). This document corrects a telephone number correction for the National Service Center for Environmental Publications (NSCEP).

FOR FURTHER INFORMATION CONTACT: For further information contact the Technical Information Staff, National Center for Environmental Assessment/ Washington Office (8623D), U.S. Environmental Protection Agency, 1200

Pennsylvania Avenue, NW.,
Washington, DC 20460. Telephone:
202-564-3261; fax: 202-565-0050.

Correction

In the **Federal Register** of August 14, 2002, in FR Doc. 02-20581, on page 53001, in the first column, correct the **ADDRESSES** caption to read:

ADDRESSES: The document is available electronically through the NCEA Web site at (www.epa.gov/ncea) under the *Publications* menus. A limited number of paper copies will be available from EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, Ohio 45242; telephone: 1-800-490-9198 or 513-489-8190; facsimile: 513-489-8695. Please provide your name and mailing address and the title and EPA number of the requested publication.

Dated: August 16, 2002.

Art Payne,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 02-21425 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0182; FRL-7193-5]

Guidance for Developing and Performing Quality Control of Water Modeling Standard Scenarios and Standard Scenario Metadata Files; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is soliciting comments on two documents, "PRZM Field and Orchard Crop Scenario Metadata" and "Standard Procedures for Conducting Quality Control and Quality Assurance for Pesticide Root Zone Model (PRZM) Field and Orchard Crop Scenarios." Interested parties may request a copy of the draft proposed procedures and scenario documentation as a set in Unit I.B. of this notice. The PRZM Field and Orchard Crop Scenario Metadata documents the crop-specific parameters (specific value used and its reference) which are key elements of the exposure scenario used to determine surface water concentrations in ecological and drinking water assessments. Standard Procedures for Conducting Quality Control and Quality Assurance for PRZM Field and Orchard Crop Scenarios provides a defined set of steps (methods of selecting or estimating specific scenario values and available

references) to develop and/or ensure the quality of a crop scenario. Both documents provide a transparent description of each environmental modeling scenario and the procedures used to create them while providing consistent and reproducible products.

DATES: Comments, identified by docket ID number OPP-2002-0182, must be received on or before October 21, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0182 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Sid Abel, Environmental Fate and Effects Division (7507C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-7346; fax number: (703) 305-6309; e-mail address: abel.sid@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those who are or may be conducting surface water modeling assessments on behalf of pesticide registration, risk assessments or those who may be involved in developing information directly related to data necessary to develop a modeling scenario. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental

Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. To access information about Standard Procedures for Conducting Quality Control and Quality Assurance for Pesticide Root Zone Model (PRZM) Field and Orchard Crop Scenarios and PRZM Field and Orchard Crop Scenario Metadata, go directly to the Home Page for the Office of Pesticide Programs at: http://www.epa.gov/oppefed1/models/water/op_scenario_metadata_df_061602.htm and http://www.epa.gov/oppefed1/models/water/qa_qc_documentation_ver2.htm

2. *By mail.* You may obtain copies of these documents, and certain other related documents that might be available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0182 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described in this unit. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0182. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

The Agency is seeking comment on two documents that describe how EPA develops and uses pesticide surface water modeling scenarios in ecological and drinking water exposure and risk assessments. These documents are entitled "Pesticide Root Zone Model (PRZM) Field and Orchard Crop Scenario Metadata" and "Standard Procedures for Conducting Quality Control and Quality Assurance for PRZM Field and Orchard Crop

Scenarios" and can be found at the following web addresses: http://www.epa.gov/oppefed1/models/water/op_scenario_metadata_df_061602.htm and http://www.epa.gov/oppefed1/models/water/qa_qc_documentation_ver2.htm

Modeling scenarios are defined as the set of characteristics of the agricultural crop to which a pesticide may be applied (e.g., cotton) and the field information on which the crop is actually grown (e.g., soils) that are necessary to estimate pesticide transport to surface water. The modeling sites, or scenarios, the OPP uses to estimate environmental concentrations in surface water are documented in and developed through the use of these documents.

These documents were developed to support the following activities: OP Cumulative Risk Assessment, the Agency's Information Quality Guideline, data quality guidelines and to improve environmental assessments.

The first document, "PRZM Field and Orchard Crop Scenario Metadata," provides a detailed listing of the parameters and associated values specific to a crop and field combination (e.g., a cotton field in Yazoo County, Mississippi). OPP evaluated several approaches to documenting the parameters from a modeling scenario used to estimate environmental exposures. This format is believed to provide the most appropriate means to readily document and recall critical information contained in a given scenario. Users of this format, whether Agency staff or the public, will be able to quickly document a scenario in a consistent manner that meets quality standards implemented by the OPP. In addition, users who retrieve information or wish to understand the content of a crop-field scenario for a pesticide assessment will be assured of a standardized format which simplifies review. Information in this document reflects the results of the second document "Standard Procedures for Conducting Quality Control and Quality Assurance for PRZM Field and Orchard Crop Scenarios."

Standard Procedures for Conducting Quality Control and Quality Assurance for PRZM Field and Orchard Crop Scenarios describes the set of procedures, methods, and references to "construct" or review for consistency the information contained in a crop-field scenario. The steps and recommendation described in this guidance provide a sound scientific basis for selecting information with relevance to what is observed in an actual agricultural field such as cotton. The methodology is intended to give the

regulated community, decision-makers and the public confidence that assessments resulting from the use of scenarios representing an agricultural field reflect conditions that are likely to occur in the "real world." Numerous methods and sources of credible scientific information are given in this document and are considered readily available to the public through voice contact, public information sources (e.g., public libraries) or the world wide web. The Agency has identified and described as best possible information to support this guidance and seeks comments on what additional information would help improve modeling scenarios.

List of Subjects

Environmental protection, Environmental modeling, Pesticide Root Zone Model, PRZM, Surface water exposure, Pesticides, Crops, Modeling Guidance.

Dated: August 5, 2002.

Sidney Abel, III,

Chief, Environmental Risk Branch I, Office of Pesticide Programs.

[FR Doc. 02-20874 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7264-3]

Peak Oil Superfund Site; Notice of Proposed de Minimis Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed de minimis settlement.

SUMMARY: Under section 122(g)(4) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the Environmental Protection Agency has offered a de minimis settlement at the Peak Oil Superfund Site (Site) under an Administrative Order on Consent (AOC) to settle claims for past and future response costs at the Site. Approximately 263 parties have returned signature pages accepting EPA's settlement offer. For thirty (30) days following the publication of this notice, EPA will receive written comments relating to the settlement. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper, or inadequate. Copies of the proposed settlement are available from:

Ms. Paula V. Batchelor, U.S. Environmental Protection Agency, Region IV, CERCLA Program Services Branch, Waste Management Division, 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562-8887.

Comments should reference the Peak Oil Superfund Site, Tampa, Florida, and EPA Docket No. CER-04-2002-3753. Written comments may be submitted to Mr. Greg Armstrong at the above address within 30 days of the date of publication.

Dated: August 8, 2002.

Anita L. Davis,

Acting Chief, CERCLA Program Services Branch, Waste Management Division.

[FR Doc. 02-21292 Filed 8-20-02; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[MM Docket No. 02-138; FCC 02-166]

Mountain Wireless, Inc. and Clear Channel Broadcasting License, Inc.

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the FCC designates the applications to assign the licenses of radio stations WSKW(AM) and WHQO(FM), Skowhegan, Maine, from Mountain Wireless, Inc. ("Mountain") to Clear Channel Broadcasting Licenses, Inc. ("Clear Channel"). The Commission cannot find, based on the record, that grant of these applications is consistent with the public interest, convenience, and necessity. Accordingly, pursuant to 47 U.S.C. 309(e), the Commission designates the applications for hearing to determine whether the public interest, convenience, and necessity will be served by grant of the applications.

DATES: See **SUPPLEMENTARY INFORMATION** section for document filing dates.

ADDRESSES: Please file documents with the Investigations and Hearing Division, Enforcement Bureau, Federal Communications Commission, Room 3-B431, 445 12th Street, SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Charles W. Kelley, Chief, Investigations and Hearing Division, Enforcement Bureau, at (202) 418-1420.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's Hearing Designation Order, MM Docket No. 02-138, adopted on June 5, 2002 and released on July 10, 2002. The full text

is available for inspection and copying during normal business hours in the FCC Reference Information Center, Room CY-A257, 445 12th Street, SW, Washington, DC 20554. The full text may also be purchased from the Commission's copy contractor, Qualex International, Room CY-B402, 445 12th Street, SW, Washington, DC 20554, telephone (202) 863-2983, facsimile (202) 863-2898, or via e-mail at qualexint@aol.com, or may be viewed via the internet at: http://www.fcc.gov/Document_Indexes/Media/2002_index_MB_Order.html. Alternative formats are available to persons with disabilities by contacting Martha Contee at (202) 418-0260 or TTY (202) 418-2555.

Synopsis of the Order

1. In March 1996, the Commission relaxed the numerical station limits in its local radio ownership rule in accordance with Congress's directive in section 202(b) of the Telecommunications Act of 1996. Since then, the Commission has received applications proposing transactions that would comply with the new limits, but that nevertheless could produce concentration levels that raised significant concerns about the potential impact on the public interest. In response to these concerns, the Commission concluded that it has an independent obligation to consider whether a proposed pattern of radio ownership that complies with the local radio ownership limits would otherwise have an adverse competitive effect in a particular local radio market and thus would be inconsistent with the public interest. In August 1998, the Commission also began flagging public notices of radio station transactions that would result in one entity controlling 50 percent or more of the advertising revenues in the relevant Arbitron radio market or two entities controlling 70 percent or more of the advertising revenues in that market. On November 8, 2001, we adopted the Notice of Proposed Rulemaking in MM Docket No. 01-317, 16 FCC Rcd 19861 (2001), 66 FR 63986, December 11, 2001 ("Local Radio Ownership NPRM"). We expressed concern that our current policies on local radio ownership did not adequately reflect current industry conditions and had led to unfortunate delays in the processing of assignment and transfer applications. Accordingly, we adopted the *Local Radio Ownership NPRM* to undertake a comprehensive examination of our rules and policies concerning local radio ownership and to develop a new framework that will be more responsive to current marketplace

realities while continuing to address our core public interest concerns of promoting diversity and competition. In the *Local Radio Ownership NPRM*, we also set forth an interim policy to guide our actions on radio assignment and transfer of control applications pending a decision in that proceeding. Under our interim policy, we presume that an application that falls below the 50/70 screen will not raise competition concerns unless a petition to deny raising competition issues is filed. For applications identified by the 50/70 screen, the interim policy directs the Commission's staff to conduct a public interest analysis, including an independent preliminary competition analysis, and sets forth generic areas of inquiry for this purpose. The interim policy also sets forth timetables for staff recommendations to the Commission for the disposition of cases that may raise competition concerns.

2. On September 18, 2001, Mountain and Clear Channel filed applications proposing to assign the licenses of WSKW(AM) and WHQO(FM) from Mountain to Clear Channel. The applications were unopposed. Clear Channel currently owns six stations in the Augusta-Waterville, Maine Arbitron metropolitan market ("Augusta-Waterville metro"): (1) WFAU(AM), Gardiner, Maine; (2) WABK-FM, Gardiner, Maine; (3) WCME(FM), Boothbay Harbor, Maine; (4) WIGY(FM), Madison, Maine; (5) WKCG(FM), Augusta, Maine; and (6) WTOS-FM, Skowhegan, Maine.

3. Section 310(d) of the Communications Act of 1934, as amended (the "Communications Act"), 47 U.S.C. 310(d), requires the Commission to find that the public interest, convenience and necessity would be served by the assignment of Mountain's radio broadcast licenses to Clear Channel before the assignment may occur. Under the interim policy set forth in our *Local Radio Ownership NPRM* we conduct a public interest analysis, including but not limited to an independent preliminary competition analysis of the proposed transaction based on publicly available information and information in the Commission's records. Under the interim policy, to decide whether a proposed assignment serves the public interest, we first determine whether it complies with the specific provisions of the Communications Act, other applicable statutes, and the Commission's rules, including our local radio ownership rules. If it does, we then consider any potential public interest harms of the proposed transaction as well as any potential public interest benefits to

determine whether, on balance, the assignment serves the public interest. The Commission's analysis of public interest benefits and harms includes an analysis of the potential competitive effects of the transaction, as informed by traditional antitrust principles. However, the Commission's public interest evaluation is not limited to competition concerns but necessarily encompasses the broad aims of the Communications Act. These broad aims include, among other things, ensuring the existence of an efficient, nationwide radio communications service available to everyone and promoting locally oriented service and diversity in media voices. Our public interest analysis therefore includes assessing whether the transfer will affect the quality of radio services or responsiveness to the local needs of the community, and whether it will result in the provision of new or additional services to listeners. Thus, under our interim policy, where a proposed transaction raises concerns about economic concentration, we will consider evidence that the particular circumstances of a case may mitigate any adverse impact that might otherwise result, as well as any evidence of benefits to radio listeners that might result from the proposed transaction. Ultimately, it is the potential impact of the transaction on listeners that will determine whether we can find that, on balance, grant of a particular radio station assignment or transfer of control application serves the public interest.

4. Having concluded that the proposed transaction is consistent with the numerical limits set forth in our ownership rules, we turn to our competition analysis. Here, we find that the proposed transaction would create a market in which the combined market share of the top two group owners in the market would be 99.5%. We find that Clear Channel has failed to demonstrate particular circumstances in this market sufficient to overcome a concern that this level of economic concentration in this market will harm the public interest. To the extent Clear Channel presents generic arguments challenging the parameters of our current competition analysis, we will address such concerns in the context of the *Local Radio Ownership NPRM* and need not consider them here. Rather, we look only to the record of this case to determine whether there are unique facts that persuade us that grant of these assignment applications would serve the public interest despite the apparent economic concentration it will create. On the basis of the information before us, we are unable to make the required

finding that the public interest, convenience and necessity will be served by granting the subject applications. Accordingly, we will designate the assignment applications for hearing to determine, pursuant to 47 U.S.C. 309(e), and based on the evidence to be adduced at hearing, whether the public interest, convenience and necessity will be served by the grant of the applications.

5. We direct the Administrative Law Judge ("ALJ") to examine in an evidentiary hearing the particular circumstances of the Augusta-Waterville metro to determine whether the factual assumptions in Section III.C. of the Hearing Designation Order are correct. We further direct the ALJ to determine, in light of his or her conclusions, whether the transaction is likely to cause any anticompetitive harms, and to determine what, if any, public benefits would accrue from this transaction. Finally, we direct the ALJ to apply these findings to determine whether, on balance, grant of the applications would serve the public interest.

6. To defer further consideration of the applications to assign the licenses of Stations WSKW(AM) and WHQO(FM), Skowhegan, Maine, from Mountain to Clear Channel in accordance with the interim policy, Mountain and Clear Channel must file a joint election to defer consideration of the applications. Such election must be filed by September 5, 2002.

7. In the event the parties do not timely file the joint election set forth in the paragraph above, pursuant to 47 U.S.C. 309(e), the applications to assign the licenses of Stations WSKW(AM) and WHQO(FM), Skowhegan, Maine, from Mountain to Clear Channel are designated for hearing at a time and place to be specified in a subsequent Order, to determine, in light of the evidence to be presented in the hearing, whether the public interest, convenience and necessity would be served by the grant of the above-captioned assignment applications (File Nos. BAL-20010918ABB/BALH-20010918ABC).

8. Pursuant to 47 U.S.C. 309(e), the burden of proof with respect to both the introduction of evidence and the issue specified in this Order shall be upon Mountain and Clear Channel, the applicant parties in this proceeding.

9. A copy of each document filed in this proceeding subsequent to the date of adoption of this Order must be served on the counsel of record appearing on behalf of the Chief, Enforcement Bureau. Parties may inquire as to the identity of such counsel by calling the Investigations and Hearings Division of

the Enforcement Bureau at (202) 418-1420. Such service must be addressed to the named counsel of record, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission, 445 12th Street, SW, Room 3-B431, Washington, DC 20554.

10. The effectiveness of this Order is stayed until September 11, 2002, no less than 10 days prior to which the parties may amend their applications or file such other information with the Media Bureau as they deem relevant to ameliorate the competition concerns identified in this Order.

11. To avail themselves of the opportunity to be heard, Mountain and Clear Channel, pursuant to 47 CFR 1.221(c) and 1.221(e), in person or by their respective attorneys, must file, in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this Order. Such written appearance shall be filed by September 11, 2002. Pursuant to 47 CFR 1.221(c) of the Commission's rules, if the parties fail to file an appearance within the specified time period, the assignment applications will be dismissed with prejudice for failure to prosecute.

12. The applicants, pursuant to 47 U.S.C. 311(a)(2) and 47 CFR 73.3594, must give notice of the hearing within the time and in the manner prescribed, and must advise the Commission of the publication of such notice as required by 47 CFR 73.3594(g).

13. The applications to assign the licenses of stations WSKW(AM) and WHQO(FM), Skowhegan, Maine, from Mountain to Clear Channel will be held in abeyance pending the outcome of this proceeding.

14. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send copies of this Order to all parties by Certified Mail—Return Receipt Requested.

Federal Communications Commission.

Marlene H. Dortch,
Secretary.

[FR Doc. 02-21302 Filed 8-20-02; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[MM Docket No. 02-139; FCC 02-165]

Youngstown Radio License, L.L.C. and Citicasters Licenses, Inc.

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the FCC designates the applications to assign the licenses of radio stations WNIO(AM) and WNCD(FM), Youngstown, Ohio; WICT(FM), Grove City, Pennsylvania; and WAKZ(FM), Sharpsville, Pennsylvania, from Youngstown Radio License, L.L.C. ("Youngstown Radio") to Citicasters Licenses, Inc., a wholly-owned subsidiary of Clear Channel Communications, Inc. ("Clear Channel"). The Commission cannot find, based on the record, that grant of these applications is consistent with the public interest, convenience, and necessity. Accordingly, pursuant to 47 U.S.C. 309(e), the Commission designates the applications for hearing to determine whether the public interest, convenience, and necessity will be served by grant of the applications.

DATES: See **SUPPLEMENTARY INFORMATION** section for document filing dates.

ADDRESSES: Please file documents with the Investigations and Hearing Division, Enforcement Bureau, Federal Communications Commission, Room 3-B431, 445 12th Street, SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Charles W. Kelley, Chief, Investigations and Hearing Division, Enforcement Bureau, at (202) 418-1420.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's Hearing Designation Order, MM Docket No. 02-139, adopted on June 5, 2002 and released on July 10, 2002. The full text is available for inspection and copying during normal business hours in the FCC Reference Information Center, Room CY-A257, 445 12th Street, SW., Washington, DC 20554. The full text may also be purchased from the Commission's copy contractor, Qualex International, Room CY-B402, 445 12th Street, SW., Washington, DC 20554, telephone (202) 863-2983, facsimile (202) 863-2898, or via e-mail at qualexint@aol.com, or may be viewed via the internet at: http://www.fcc.gov/Document_Indexes/Media/2002_index_MB_Order.html. Alternative formats are available to persons with disabilities by contacting Martha Contee at (202) 418-0260 or TTY (202) 418-2555.

Synopsis of the Order

1. In March 1996, the Commission relaxed the numerical station limits in its local radio ownership rule in accordance with Congress's directive in section 202(b) of the Telecommunications Act of 1996. Since

then, the Commission has received applications proposing transactions that would comply with the new limits, but that nevertheless could produce concentration levels that raised significant concerns about the potential impact on the public interest. In response to these concerns, the Commission concluded that it has an independent obligation to consider whether a proposed pattern of radio ownership that complies with the local radio ownership limits would otherwise have an adverse competitive effect in a particular local radio market and thus would be inconsistent with the public interest. In August 1998, the Commission also began flagging public notices of radio station transactions that would result in one entity controlling 50 percent or more of the advertising revenues in the relevant Arbitron radio market or two entities controlling 70 percent or more of the advertising revenues in that market. On November 8, 2001, we adopted the Notice of Proposed Rulemaking in MM Docket No. 01-317, 16 FCC Rcd 19861, 66 FR 63986, December 11, 2001 ("*Local Radio Ownership NPRM*"). We expressed concern that our current policies on local radio ownership did not adequately reflect current industry conditions and had led to unfortunate delays in the processing of assignment and transfer applications. Accordingly, we adopted the *Local Radio Ownership NPRM* to undertake a comprehensive examination of our rules and policies concerning local radio ownership and to develop a new framework that will be more responsive to current marketplace realities while continuing to address our core public interest concerns of promoting diversity and competition. In the *Local Radio Ownership NPRM*, we also set forth an interim policy to guide our actions on radio assignment and transfer of control applications pending a decision in that proceeding. Under our interim policy, we presume that an application that falls below the 50/70 screen will not raise competition concerns unless a petition to deny raising competition issues is filed. For applications identified by the 50/70 screen, the interim policy directs the Commission's staff to conduct a public interest analysis, including an independent preliminary competition analysis, and sets forth generic areas of inquiry for this purpose. The interim policy also sets forth timetables for staff recommendations to the Commission for the disposition of cases that may raise competition concerns.

2. On October 1, 1999, Youngstown Radio and Clear Channel filed

applications proposing to assign the licenses of WNIO(AM), WNCD(FM), WICT(FM), and WAKZ(FM) from Youngstown Radio to Clear Channel. The applications were unopposed. Clear Channel currently owns three stations in the Youngstown-Warren, Ohio Arbitron metropolitan market ("Youngstown-Warren metro"): (1) WMXY(FM), Youngstown, Ohio; (2) WKBN(AM), Youngstown, Ohio; and (3) WBBG(FM), Niles, Ohio.

3. Section 310(d) of the Communications Act of 1934, as amended (the "Communications Act"), 47 U.S.C. 310(d), requires the Commission to find that the public interest, convenience and necessity would be served by the assignment of Youngstown Radio's radio broadcast licenses to Clear Channel before the assignment may occur. Under the interim policy set forth in our *Local Radio Ownership NPRM* we conduct a public interest analysis, including but not limited to an independent preliminary competition analysis of the proposed transaction based on publicly available information and information in the Commission's records. Under the interim policy, to decide whether a proposed assignment serves the public interest, we first determine whether it complies with the specific provisions of the Communications Act, other applicable statutes, and the Commission's rules, including our local radio ownership rules. If it does, we then consider any potential public interest harms of the proposed transaction as well as any potential public interest benefits to determine whether, on balance, the assignment serves the public interest. The Commission's analysis of public interest benefits and harms includes an analysis of the potential competitive effects of the transaction, as informed by traditional antitrust principles. However, the Commission's public interest evaluation is not limited to competition concerns but necessarily encompasses the broad aims of the Communications Act. These broad aims include, among other things, ensuring the existence of an efficient, nationwide radio communications service available to everyone and promoting locally oriented service and diversity in media voices. Our public interest analysis therefore includes assessing whether the transfer will affect the quality of radio services or responsiveness to the local needs of the community, and whether it will result in the provision of new or additional services to listeners. Thus, under our interim policy, where a proposed transaction raises concerns

about economic concentration, we will consider evidence that the particular circumstances of a case may mitigate any adverse impact that might otherwise result, as well as any evidence of benefits to radio listeners that might result from the proposed transaction. Ultimately, it is the potential impact of the transaction on listeners that will determine whether we can find that, on balance, grant of a particular radio station assignment or transfer of control application serves the public interest.

4. Having concluded that the proposed transaction is consistent with the numerical limits set forth in our ownership rules, we turn to our competition analysis. Here, we find that the proposed transaction would create a market in which the combined market share of the top two group owners in the market would be 95.3%. We find that Clear Channel has failed to demonstrate particular circumstances in this market sufficient to overcome a concern that this level of economic concentration in this market will harm the public interest. To the extent Clear Channel presents generic arguments challenging the parameters of our current competition analysis, we will address such concerns in the context of the *Local Radio Ownership NPRM* and need not consider them here. Rather, we look only to the record of this case to determine whether there are unique facts that persuade us that grant of this assignment application would serve the public interest despite the apparent economic concentration it will create. On the basis of the information before us, we are unable to make the required finding that the public interest, convenience and necessity will be served by granting the subject applications. Accordingly, we will designate the assignment applications for hearing to determine, pursuant to 47 U.S.C. 309(e), and based on the evidence to be adduced at hearing, whether the public interest, convenience and necessity will be served by the grant of the applications.

5. We direct the Administrative Law Judge ("ALJ") to examine in an evidentiary hearing the particular circumstances of the Youngstown-Warren metro to determine whether the factual assumptions in Section III.C. of the Hearing Designation Order are correct. We further direct the ALJ to determine, in light of his or her conclusions, whether the transaction is likely to cause any anticompetitive harms, and to determine what, if any, public benefits would accrue from this transaction. Finally, we direct the ALJ to apply these findings to determine whether, on balance, grant of the

applications would serve the public interest.

6. To defer further consideration of the applications to assign the licenses of stations WNIO(AM) and WNCN(FM), Youngstown, Ohio, WICT(FM), Grove City, Pennsylvania, and WAKZ(FM), Sharpsville, Pennsylvania, from Youngstown Radio to Clear Channel in accordance with the interim policy, Youngstown Radio and Clear Channel must file a joint election to defer consideration of the applications. Such election must be filed by September 5, 2002.

7. In the event the parties do not timely file the joint election set forth in the paragraph above, pursuant to 47 U.S.C. 309(e), the applications to assign the licenses of stations WNIO(AM) and WNCN(FM), Youngstown, Ohio, WICT(FM), Grove City, Pennsylvania, and WAKZ(FM), Sharpsville, Pennsylvania, from Youngstown Radio to Clear Channel are designated for hearing at a time and place to be specified in a subsequent Order, to determine, in light of the evidence to be presented in the hearing, whether the public interest, convenience and necessity would be served by the grant of the above-captioned assignment applications (File Nos. BAL/BALH-19991001ABM-ABP).

8. Pursuant to 47 U.S.C. 309(e), the burden of proof with respect to both the introduction of evidence and the issue specified in this Order shall be upon Youngstown Radio and Clear Channel, the applicant parties in this proceeding.

9. A copy of each document filed in this proceeding subsequent to the date of adoption of this Order must be served on the counsel of record appearing on behalf of the Chief, Enforcement Bureau. Parties may inquire as to the identity of such counsel by calling the Investigations and Hearings Division of the Enforcement Bureau at (202) 418-1420. Such service must be addressed to the named counsel of record, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission, 445 12th Street, SW, Room 3-B431, Washington, DC 20554.

10. The effectiveness of this Order is stayed until September 11, 2002, no less than 10 days prior to which the parties may amend their applications or file such other information with the Media Bureau as they deem relevant to ameliorate the competition concerns identified in this Order.

11. To avail themselves of the opportunity to be heard, Youngstown Radio and Clear Channel, pursuant to 47 CFR 1.221(c) and 1.221(e), in person or by their respective attorneys, must file,

in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this Order. Such written appearance shall be filed by September 11, 2002. Pursuant to 47 CFR 1.221(c), if the parties fail to file an appearance within the specified time period, the assignment applications will be dismissed with prejudice for failure to prosecute.

12. The applicants, pursuant to 47 U.S.C. 311(a)(2) and 47 CFR 73.3594, must give notice of the hearing within the time and in the manner prescribed, and must advise the Commission of the publication of such notice as required by 47 CFR 73.3594(g).

13. The applications to assign the licenses of stations WNIO(AM) and WNCN(FM), Youngstown, Ohio, WICT(FM), Grove City, Pennsylvania, and WAKZ(FM), Sharpsville, Pennsylvania, from Youngstown Radio to Clear Channel will be held in abeyance pending the outcome of this proceeding.

14. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send copies of this Order to all parties by Certified Mail—Return Receipt Requested.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 02-21303 Filed 8-20-02; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[MM Docket No. 02-137; FCC 02-167]

Sheldon Broadcasting, Ltd. and Clear Channel Broadcasting License, Inc.

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the FCC designates the application to assign the license of radio station KLFX(FM), Nolanville, Texas, from Sheldon Broadcasting, Ltd. ("Sheldon" to Clear Channel Broadcasting Licenses, Inc. ("Clear Channel"). The Commission cannot find, based on the record, that grant of this application is consistent with the public interest, convenience, and necessity. Accordingly, pursuant to 47 U.S.C. 309(e), the Commission designates the application for hearing to determine whether the public interest, convenience, and necessity will be served by grant of the application.

DATES: SEE SUPPLEMENTARY INFORMATION section for document filing dates.

ADDRESSES: Please file documents with the Investigations and Hearing Division, Enforcement Bureau, Federal Communications Commission, Room 3-B431, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Charles W. Kelley, Chief, Investigations and Hearing Division, Enforcement Bureau, at (202) 418-1420.

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Synopsis of the Order

1. In March 1996, the Commission relaxed the numerical station limits in its local radio ownership rule in accordance with Congress's directive in section 202(b) of the Telecommunications Act of 1996. Since then, the Commission has received applications proposing transactions that would comply with the new limits, but that nevertheless could produce concentration levels that raised significant concerns about the potential impact on the public interest. In response to these concerns, the Commission concluded that it has an independent obligation to consider whether a proposed pattern of radio ownership that complies with the local radio ownership limits would otherwise have an adverse competitive effect in a particular local radio market and thus would be inconsistent with the public interest. In August 1998, the Commission also began flagging public notices of radio station transactions that would result in one entity controlling 50 percent or more of the advertising revenues in the relevant Arbitron radio market or two entities controlling 70 percent or more of the advertising revenues in that market. On November

8, 2001, we adopted the Notice of Proposed Rulemaking in MM Docket No. 01-317, 16 FCC Rcd 19861, 66 FR 63986, December 11, 2001 ("*Local Radio Ownership NPRM*"). We expressed concern that our current policies on local radio ownership did not adequately reflect current industry conditions and had led to unfortunate delays in the processing of assignment and transfer applications. Accordingly, we adopted the *Local Radio Ownership NPRM* to undertake a comprehensive examination of our rules and policies concerning local radio ownership and to develop a new framework that will be more responsive to current marketplace realities while continuing to address our core public interest concerns of promoting diversity and competition. In the *Local Radio Ownership NPRM*, we also set forth an interim policy to guide our actions on radio assignment and transfer of control applications pending a decision in that proceeding. Under our interim policy, we presume that an application that falls below the 50/70 screen will not raise competition concerns unless a petition to deny raising competition issues is filed. For applications identified by the 50/70 screen, the interim policy directs the Commission's staff to conduct a public interest analysis, including an independent preliminary competition analysis, and sets forth generic areas of inquiry for this purpose. The interim policy also sets forth timetables for staff recommendations to the Commission for the disposition of cases that may raise competition concerns.

2. On August 13, 2001, Clear Channel and Sheldon filed an application proposing to assign the license of station KLFX(FM) from Sheldon to Clear Channel. The application was unopposed. Clear Channel currently is the licensee of two stations in the Killeen-Temple, Texas Arbitron metro: KASZ(FM), Gatesville, Texas, and KIIZ(FM), Killeen, Texas.

3. Section 310(d) of the Communications Act of 1934, as amended (the "Communications Act"), 47 U.S.C. 310(d), requires the Commission to find that the public interest, convenience and necessity would be served by the assignment of Sheldon's radio broadcast license to Clear Channel before the assignment may occur. Under the interim policy set forth in our *Local Radio Ownership NPRM*, we conduct a public interest analysis, including but not limited to an independent preliminary competition analysis of the proposed transaction based on publicly available information and information in the Commission's records. Under the interim policy, to

decide whether a proposed assignment serves the public interest, we first determine whether it complies with the specific provisions of the Communications Act, other applicable statutes, and the Commission's rules, including our local radio ownership rules. If it does, we then consider any potential public interest harms of the proposed transaction as well as any potential public interest benefits to determine whether, on balance, the assignment serves the public interest. The Commission's analysis of public interest benefits and harms includes an analysis of the potential competitive effects of the transaction, as informed by traditional antitrust principles. However, the Commission's public interest evaluation is not limited to competition concerns but necessarily encompasses the broad aims of the Communications Act. These broad aims include, among other things, ensuring the existence of an efficient, nationwide radio communications service available to everyone and promoting locally oriented service and diversity in media voices. Our public interest analysis therefore includes assessing whether the transfer will affect the quality of radio services or responsiveness to the local needs of the community, and whether it will result in the provision of new or additional services to listeners. Thus, under our interim policy, where a proposed transaction raises concerns about economic concentration, we will consider evidence that the particular circumstances of a case may mitigate any adverse impact that might otherwise result, as well as any evidence of benefits to radio listeners that might result from the proposed transaction. Ultimately, it is the potential impact of the transaction on listeners that will determine whether we can find that, on balance, grant of a particular radio station assignment or transfer of control application serves the public interest.

4. Having concluded that the proposed transaction is consistent with the numerical limits set forth in our ownership rules, we turn to our competition analysis. Here, we find that the proposed transaction would create a market in which the combined market share of the top two group owners in the market would be 98.2%. We find that Clear Channel has failed to demonstrate particular circumstances in this market sufficient to overcome a concern that this level of economic concentration in this market will harm the public interest. To the extent Clear Channel presents generic arguments challenging the parameters of our current competition analysis, we will address

such concerns in the context of the *Local Radio Ownership NPRM* and need not consider them here. Rather, we look only to the record of this case to determine whether there are unique facts that persuade us that grant of this assignment application would serve the public interest despite the apparent economic concentration it will create. On the basis of the information before us, we are unable to make the required finding that the public interest, convenience and necessity will be served by granting the subject application. Accordingly, we will designate the assignment applications for hearing to determine, pursuant to 47 U.S.C. 309(e), and based on the evidence to be adduced at hearing, whether the public interest, convenience and necessity will be served by the grant of the application.

5. We direct the Administrative Law Judge ("ALJ") to examine in an evidentiary hearing the particular circumstances of the Killeen-Temple, Texas metro to determine whether the factual assumptions in Section III.C. of the Hearing Designation Order are correct. We further direct the ALJ to determine, in light of his or her conclusions, whether the transaction is likely to cause any anticompetitive harms, and to determine what, if any, public benefits would accrue from this transaction. Finally, we direct the ALJ to apply these findings to determine whether, on balance, grant of the application would serve the public interest.

6. To defer further consideration of the application to assign the license of station KLFX(FM), Nolanville, Texas, from Sheldon to Clear Channel in accordance with the interim policy, Sheldon and Clear Channel must file a joint election to defer consideration of the application. Such election must be filed by September 5, 2002.

7. In the event the parties do not timely file the joint election set forth in the paragraph above, pursuant to 47 U.S.C. 309(e), the application to assign the license of station KLFX(FM), Nolanville, Texas, from Sheldon to Clear Channel is designated for hearing at a time and place to be specified in a subsequent Order, to determine, in light of the evidence to be presented in the hearing, whether the public interest, convenience and necessity would be served by the grant of the above-captioned assignment application (File No. BALH-20010813AAM).

8. Pursuant to 47 U.S.C. 309(e), the burden of proof with respect to both the introduction of evidence and the issue specified in this Order shall be upon

Sheldon and Clear Channel, the applicant parties in this proceeding.

9. A copy of each document filed in this proceeding subsequent to the date of adoption of this Order must be served on the counsel of record appearing on behalf of the Chief, Enforcement Bureau. Parties may inquire as to the identity of such counsel by calling the Investigations and Hearings Division of the Enforcement Bureau at (202) 418-1420. Such service must be addressed to the named counsel of record, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission, 445 12th Street, SW, Room 3-B431, Washington, DC 20554.

10. The effectiveness of this Order is stayed until September 10, 2002, no less than 10 days prior to which the parties may amend their application or file such other information with the Media Bureau as they deem relevant to ameliorate the competition concerns identified in this Order.

11. To avail themselves of the opportunity to be heard, Sheldon and Clear Channel, pursuant to 47 CFR 1.221(c) and 1.221(e), in person or by their respective attorneys, must file, in triplicate, a written appearance stating an intention to appear on the date fixed for the hearing and present evidence on the issues specified in this Order. Such written appearance shall be filed by September 10, 2002. Pursuant to 47 CFR 1.221(c) of the Commission's rules, if the parties fail to file an appearance within the specified time period, the assignment application will be dismissed with prejudice for failure to prosecute.

12. The applicants, pursuant to 47 U.S.C. 311(a)(2), and 47 CFR 73.3594 must give notice of the hearing within the time and in the manner prescribed, and must advise the Commission of the publication of such notice as required by 47 CFR 73.3594(g).

13. The application to assign the licenses of station KLFX(FM), Nolanville, Texas, from Sheldon to Clear Channel will be held in abeyance pending the outcome of this proceeding.

14. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send copies of this Order to all parties by Certified Mail—Return Receipt Requested.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 02-21339 Filed 8-20-02; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2569]

Petitions for Reconsideration of Action in Rulemaking Proceedings

August 13, 2002.

Petitions for Reconsideration have been filed in the Commission's rulemaking proceedings listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of this document is available for viewing and copying in Room CY-A257, 445 12th Street, SW., Washington, DC or may be purchased from the Commission's copy contractor, Qualex International (202) 863-2893. Oppositions to these petitions must be filed by September 5, 2002. See § 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: In the Matter of Telecommunications Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities (CC Docket No. 98-67).

Number of Petitions Filed: 2.

Subject: In the Matter of Amendment of Part 15 of the Commission's Rules Regarding Spread Spectrum Devices (ET Docket No. 99-231).

Number of Petitions Filed: 1.

Subject: In the Matter of Amendment of Eligibility Requirements in Part 78 Regarding 12 GHz Cable Television Relay Service (CS Docket No. 99-250, RM-9257).

Number of Petitions Filed: 1.

Marlene H. Dortch,

Secretary.

[FR Doc. 02-21213 Filed 8-20-02; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011793-001.

Title: Maersk Sealand/Great Western Asia-U.S. West Coast Slot Charter Agreement.

Parties: A.P. Moller-Maersk Sealand, Great Western Steamship Company.
Synopsis: The amendment to the agreement provides for regularly scheduled service in place of the previous ad hoc service.

By Order of the Federal Maritime Commission.

Dated: August 16, 2002.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 02-21336 Filed 8-20-02; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding date shown below:

License Number: 3978F
Name: AIS Gator Exports, Inc.
Address: 201 Springsong Road, Lithia, FL 33547
Date Revoked: May 2, 2002.
Reason: Failed to maintain a valid bond.

License Number: 13273N
Name: ATF Cargo International, Inc.
Address: 1683 Galvez Avenue, San Francisco, CA 94124
Date Revoked: July 21, 2002.
Reason: Failed to maintain a valid bond.

License Number: 4033F
Name: Ayma Cargo Corp.
Address: 10854 NW 29th, Suite 200, Miami, FL 33172
Date Revoked: July 6, 2002.
Reason: Failed to maintain a valid bond.

License Number: 17391N
Name: Amfak Global Services, Inc.
Address: 205 Meadow Road, Edison, NJ 08817
Date Revoked: July 28, 2002.
Reason: Failed to maintain a valid bond.

License Number: 15306N
Name: Buyers Express, Inc.
Address: 6000 Carnegie Blvd., Charlotte, NC 28209
Date Revoked: July 10, 2002.
Reason: Failed to maintain a valid bond.

License Number: 8670N
Name: C.V.S. Enterprises, Inc.
Address: 8390 Faust Avenue, West Hills, CA 91304

Date Revoked: July 10, 2002.
Reason: Failed to maintain a valid bond.

License Number: 11995N
Name: Calinex Shipping, Inc.
Address: 500 W. 140th Street, Gardena, CA 90248
Date Revoked: June 28, 2002.
Reason: Failed to maintain a valid bond.

License Number: 16961N
Name: Cargo Network Express, Inc.
Address: 2801 N.W. 74th Avenue, #216, Miami, FL 33122
Date Revoked: June 9, 2002.
Reason: Failed to maintain a valid bond.

License Number: 16448N
Name: Delpa International Corp.
Address: 7084 N.W. 50th Street, Miami, FL 33166
Date Revoked: August 9, 2002.
Reason: Failed to maintain a valid bond.

License Number: 11959N
Name: ESBO Shipping Inc.
Address: 175-01 Rockaway Blvd., Suite 205, Jamaica, NY 11434
Date Revoked: July 6, 2002.
Reason: Failed to maintain a valid bond.

License Number: 15753N
Name: Eagle Logistics, Inc.
Address: 534 Merrick Road, Suite 1, Lynbrook, NY 11563
Date Revoked: July 24, 2002.
Reason: Failed to maintain a valid bond.

License Number: 16844N
Name: Estes Express Lines, Inc.
Address: P.O. Box 25612, 1100 E. Commerce Road, Richmond, VA 23224
Date Revoked: July 31, 2002.
Reason: Failed to maintain a valid bond.

License Number: 3240F
Name: Freight Connections International, Ltd.
Address: 935 West 175th Street, Homewood, IL 60430-2028
Date Revoked: June 30, 2002.
Reason: Surrendered license voluntarily.

License Number: 13271N
Name: Gallagher Transfer & Storage Company, Inc.
Address: 2401 Elysian Fields Avenue, New Orleans, LA 70117
Date Revoked: July 10, 2002.
Reason: Failed to maintain a valid bond.

License Number: 15134N
Name: Internavigation, Inc.
Address: 229 N. Central Avenue, Suite 609, Glendale, CA 91203
Date Revoked: June 15, 2002.
Reason: Failed to maintain a valid bond.

License Number: 16893N
Name: Jenkar International Freight Ltd. dba American Express Line
Address: 150-30 132nd Avenue, Jamaica, NY 11434
Date Revoked: July 28, 2002.
Reason: Failed to maintain a valid bond.

License Number: 15269N
Name: Marine Logistics Incorporated
Address: 15110 Ripplewind Drive, Houston, TX 77068
Date Revoked: July 25, 2002.
Reason: Failed to maintain a valid bond.

License Number: 17350N
Name: Millenium Transportation Group, Inc.
Address: 1901 E. Lambert Road, Suite 104, La Habra, CA 90631
Date Revoked: August 7, 2002.
Reason: Failed to maintain a valid bond.

License Number: 15655N
Name: Millennium Plus, Inc.
Address: 10910 S. La Cienega Blvd., Inglewood, CA 90304
Date Revoked: August 9, 2002.
Reason: Failed to maintain a valid bond.

License Number: 17498N
Name: Newkor America, Inc. dba Trans Bay
Address: 625 W. Victoria Street, Compton, CA 90220
Date Revoked: August 9, 2002.
Reason: Failed to maintain a valid bond.

License Number: 17135N
Name: Next Day Cargo, Inc.
Address: 8805 N.W. 35th Lane, Miami, FL 33172
Date Revoked: July 25, 2002.
Reason: Failed to maintain a valid bond.

License Number: 16758N
Name: Nexttrans International, Inc.
Address: 19550 Dominguez Hills Drive, Rancho Dominguez, CA 90220
Date Revoked: July 7, 2002.
Reason: Failed to maintain a valid bond.

License Number: 13709N
Name: Pac West Trading & Transport, Inc. dba Pacwest Transport
Address: 2531 West 237th Street, Suite 122, Torrance, CA 90505
Date Revoked: August 9, 2002.
Reason: Failed to maintain a valid bond.

License Number: 17497N
Name: Palumbo USA Miami, Inc.
Address: 8405 N.W. 53rd Street, Suite B-220, Koger Center, Athens Bldg., Miami, FL 33166
Date revoked: July 27, 2002.
Reason: Failed to maintain a valid bond.

License number: 12282N
Name: Philippine Islands Cargo Transport, U.S.A.
Address: 542 Sally Lee Avenue, Azusa, CA 91702-5344
Date revoked: July 3, 2002.
Reason: Failed to maintain a valid bond.

License number: 17268N.
Name: RCM International Shipping U.S.A., L.L.C.
Address: 10-C West Access Road, Kenner, LA 70062.
Date revoked: July 18, 2002.
Reason: Failed to maintain a valid bond.

License number: 15926F.
Name: Safcomar Inc.
Address: One Exchange Place, Suite 402, Jersey City, NJ 07302.
Date revoked: June 9, 2002.
Reason: Failed to maintain a valid bond.

License number: 17257N.
Name: Sea-Go International Inc.
Address: 400 Washington Street, Mt. Holly, NJ 08060.
Date revoked: June 28, 2002.
Reason: Failed to maintain a valid bond.

License number: 17505N.

Name: Trans Logistics, Inc. dba World Express
Address: 520 E. Carson Plaza Ct., Suite 205, Carson, CA 90746.
Date revoked: August 1, 2002.
Reason: Failed to maintain a valid bond.

License number: 17836N.
Name: U.S. Sea Wave Express, Inc.
Address: 2931 Plaza Del Amo, #74, Torrance, CA 90503.
Date revoked: August 4, 2002.
Reason: Failed to maintain a valid bond.

License number: 16716N.
Name: Ventana Cargo USA, Inc.
Address: 182-08 149th Avenue, Jamaica, NY 11413.
Date revoked: July 24, 2002.
Reason: Operating without a qualifying individual.

License number: 14235N.
Name: Village Traders, Ltd.
Address: 22428 Thunderbird Place, Hayward, CA 94545.
Date revoked: August 1, 2002.
Reason: Failed to maintain a valid bond.

License number: 6941N.
Name: Worldwide Freight System, Inc.

Address: 2401 Utah Avenue South, Suite 200, Seattle, WA 98275.
Date revoked: July 13, 2002.
Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,
Director, Bureau of Consumer Complaints and Licensing.
 [FR Doc. 02-21335 Filed 8-20-02; 8:45 am]
BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuances

Notice is hereby given that the following Ocean Transportation Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984, as amended by the Ocean Shipping Reform Act of 1998 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR 515.

License No.	Name/address	Date reissued
16426N	First Express International Corp., 148-36 Guy R. Brewer Blvd., Suite 200, Jamaica, NY 11434.	May 25, 2002.
16171N	Pecton Air Freight (USA) Inc., 175-01 Rockaway Blvd., Rm. 215, Jamaica, NY 11434	May 25, 2002.
1457F	Schmidt, Pritchard & Co., Inc., 9801 West Lawrence Avenue, Schiller Park, IL 60176	May 23, 2002.

Sandra L. Kusumoto,
Director, Bureau of Consumer Complaints and Licensing.
 [FR Doc. 02-21338 Filed 8-20-02; 8:45 am]
BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicant:
 NSCP Cargo Corporation, 23595 Cabot Blvd., Suite 116, Hayward, CA 94545.
Officers: Guillermo E. Pena, Compliance Officer, (Qualifying Individual), Arion Alabado, Director.

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants:
 ILS-International Logistics Solutions, Inc., 1337 East Rock Wren Road, Phoenix, AZ 85048.
Officer: Larry Nass, President, (Qualifying Individual), Tons Consolidators, Inc., 4309 Rousseau Lane, Palos Verdes Peninsula, CA 90274.
Officers: Ellen, Ling Ying Chen, Secretary, (Qualifying Individual), Hong Wai Tung, President.
 Ocean Freight Forwarder—Ocean Transportation Intermediary Applicant:
 A.O.C.H. Services Corp., 24 North

Road, Stony Brook, NY 11790.
Officer: Joseph A. Costanzo, President, (Qualifying Individual).
 Dated: August 16, 2002.

Bryant L. VanBrakle,
Secretary.
 [FR Doc. 02-21337 Filed 8-20-02; 8:45 am]
BILLING CODE 6730-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Invitation To Submit Quality Measures to AHRQ's National Quality Measures Clearinghouse

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: In response to its legislative mandate to compile health care quality measures (see Background section below), the Agency for Healthcare Research and Quality (AHRQ) invites

organizations, and other developers of health care quality measures to submit tested (and/or valid and reliable) quality measures for inclusion in the World Wide Web-based National Quality Measures Clearinghouse (NQMC).

AHRQ is sponsoring the development of NQMC to promote widespread access to quality measures by the health care community and other interested individuals. NQMC is designed to be a database for information on specific health care quality measures and measure sets. The scheduled availability date for the NQMC Web site is December/Winter 2002.

Measure developers are asked to submit measures and measure updates that meet the NQMC inclusion criteria, along with supporting documentation, on an ongoing basis. NQMC will contain descriptive summaries of each measure catalogued in the NQMC database. Developers have the option of making their entire measure available through NQMC or may opt to provide ordering information that NQMC will include in the measure summary. NQMC users will be directed to contact the measure developer to obtain or purchase the entire measure if it is not available via the NQMC Web site. Quality measure summaries will be retrievable by many parameters including topic, target population, and setting of care. Users of NQMC will be able to search NQMC and the National Guideline Clearinghouse™ www.guideline.gov.—simultaneously.

DATES: Quality measures and measure sets will be received on an ongoing basis by ECRI at the address below. ECRI, a nonprofit health services research organization, will perform the technical work of the NQMC, under contract with AHRQ.

ADDRESSES: Organizations interested in contributing to the NQMC should submit two hard copies of each measure and documentation that the measure meets the NQMC Inclusion Criteria in typed format and electronic (if available), including name, address, phone, and e-mail address of a contact person to: Vivian H. Coates, NQMC Project Director, ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462–1298.

FOR FURTHER INFORMATION CONTACT: Forward questions to qualitymeasures@ahrq.gov.

SUPPLEMENTARY INFORMATION:

Background

AHRQ is the lead Federal agency for enhancing the quality, appropriateness, and effectiveness of healthcare services and access to such services. In carrying out its mission, AHRQ conducts and supports research that develops and

presents scientific evidence on methods for measuring quality and strategies for improving quality. Under section 912(a)(2)(C) Title IX, of the Agency for Healthcare Research and Quality Act of 1999, AHRQ is charged with compiling health care quality measures that have been developed in the public and private sector. To this end AHRQ will compile and present measures in the NQMC that have been submitted by the public and private sector, and that meet the following definitions and inclusion criteria.

As part of its mandate to use existing technologies to promote health care quality improvement, NQMC will use the World Wide Web to effectively and efficiently reach a broad audience within the health care community. This Web-based repository of quality measures is intended to facilitate quick identification and access to quality measures by practitioners and health related organizations [e.g., third party payers, peer review groups, professional societies submitting measures]. The measures will in turn be used to make assessments that may ultimately inform health care decisions.

Quality Measure Definition

The NQMC defines a quality measure as a mechanism to assign a quantifier to quality of care by comparison to a criterion.

Criteria

A measure must meet all of the following criteria to be included in the NQMC. If the measures do not meet one or more of these inclusion criteria, the submission forms will be returned to the submitter with a request for further documentation or development in the identified area. The submitter may revise and resubmit measures.

1. The quality measure must address some aspect(s) of quality of care delivered to defined patients by a defined individual, group of individuals or organizations and must relate to at least one of the following domains: (a) Process of care (a health care service provided to or on behalf of a patient); (b) Outcome of care (a health state of a patient resulting from health care); (c) Access to care (the patient's attainment of timely and appropriate health care); and, (d) Patient experience of care (a report by a patient concerning observations of and participation in health care).

2. The submitter must provide English-language documentation that includes at least each of the three following items: (i) The rationale for the measure (The rationale is a brief statement describing the patients and

the specific aspect of health care to which the measure applies. The rationale may also include the evidence basis for the measure, and an explanation of how to interpret results, if that information is provided.); (ii) A description of the denominator and numerator of the measure (including specific variables for inclusion or exclusion of cases from either the denominator or numerator). Note—a continuous variable statement (e.g., “time to thrombolysis”) may be an acceptable alternative and measures whose metric is other than a rate or percentage will be considered on an individual basis; and, (iii) The data source(s) for the measure.

3. The submitter should provide documentation of supporting evidence appropriate for the measure domain: (1) For process measures, evidence that the measured clinical process has led to improved health outcomes; (2) For outcome measures, evidence that the outcome measure has been used to detect the impact of one or more clinical interventions; (3) For access measures, evidence that an association exists between the result of the access measure and the outcomes of or satisfaction with care; and (4) For patient experience measures, evidence that an association exists between the measure of patient experience of health care and the values and preferences of patients/consumers.

The documentation must consist of at least one of the following types of evidence: (1) One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal; (2) A systematic review of the clinical literature; (3) A clinical practice guideline or other peer-reviewed synthesis of the clinical evidence; (4) A formal consensus procedure involving expert clinicians and clinical researchers.

Additionally, for patient experience measures, evidence should include focus groups involving patients and/or cognitive testing of the measures by patients. For access measures, the consensus panel should also include other relevant stakeholders.

4. At least one of the following criteria must be satisfied with specific information attached in each case: (1) The measure has been cited in one or more reports in a National Library of Medicine (NLM) indexed, peer-reviewed journal, applying or evaluating the measure's properties; (2) The submitter provides documented peer-reviewed evidence evaluating the reliability (the degree to which the measure is free from random error) and validity (the degree to which the measure is associated with what it

purports to measure) of the measure; or (3) The measure has been developed, adopted, adapted, or endorsed by an organization that promotes rigorous development and use of clinical performance measures. Such an organization may be at the international, National, regional, State or local levels (e.g., a multi-state consortium, a State Medicaid agency, or a health organization or delivery system). **Note**—Adapted measures are those measures developed by one organization, and then subsequently adopted and modified in some way by another organization.

5. The measure must be in current use or currently in pilot testing and must be the most recent version if the measure has been revised. A measure is in current use if at least one health care organization has used the measure to evaluate or report on quality of care within the previous three years.

Dated: August 15, 2002.

Carolyn M. Clancy,

Acting Director.

[FR Doc. 02-21326 Filed 8-20-02; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02039]

Expansion of HIV/AIDS/STD Prevention and Support in the Royal Government of Cambodia; Notice of Award of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the award of fiscal year (FY) 2002 funds for a Cooperative Agreement with the Ministry of Health (MOH), Royal Government of Cambodia (Cambodia), for the improvement and expansion of HIV/AIDS/STD prevention and support activities in Cambodia.

The purpose of this cooperative agreement is to improve and expand laboratory capacity and coordination of HIV prevention activities with the MOH and among non-governmental organizations (NGOs) in Cambodia. This will be accomplished through cooperation between CDC Cambodia, the MOH, National Center for HIV/AIDS Dermatology and STDs (NCHADS), National Clinic for Dermatology and STIs, as well as the MOH National Institute of Public Health (NIPH) to:

(1) Expand the national reference laboratory capacity for HIV and STD at the National Institute of Public Health.

(2) Develop national referral laboratory capacity at NCHADS.

(3) Pilot a program to integrate the various technical strategies of the Global AIDS Program at either the operational health district or the provincial health district level.

These collaborative activities could profoundly impact the scope and intensity of the implementation of the National AIDS Policy, which calls for multi-sectoral action on many fronts. Successful implementation and expansion of laboratory capacity building could substantially increase the MOH's ability to provide high quality reference and referral laboratory service and strengthen ties between NGOs and government HIV/AIDS-related programs. Successful implementation of a pilot integration project through cooperative efforts of MOH, NGOs, and CDC could eventually lead to significant improvements in coordination of HIV/AIDS prevention and care activities country-wide.

B. Eligible Applicants

The MOH is the only appropriate and qualified organization to fulfill the requirements set forth for Cambodia in this announcement because:

1. The MOH is uniquely positioned, in terms of legal authority, experience and credibility among Cambodian citizens to provide health sector HIV/AIDS/STD Prevention Activities.

2. The purpose of the announcement is to build upon an existing framework of health information and activities for which the MOH has the responsibility for implementing.

3. The MOH has been mandated by the National AIDS Authority (NAA) to coordinate and implement health sector activities necessary for the control of the HIV/AIDS epidemic in Cambodia.

4. The MOH already has established mechanisms to access health information enabling it to immediately become engaged in the activities listed in this announcement.

C. Funds

Approximately \$810,000 is being awarded in FY2002. The award will begin on or about August 1, 2002 and will be made for a 12-month budget period within a five-year project period.

D. Where to Obtain Additional Information

To obtain business management technical assistance, contact: Angelia D. Hill, Lead Grants Management Specialist, International & Territories

Acquisition & Assistance Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, MS E-09, Atlanta, GA 30341-4146. Telephone number: (770) 488-2785. FAX: (770) 488-2866. E-mail address: aph8@cdc.gov.

For program technical assistance, contact: Jack N. Spencer, Global AIDS Program (GAP), Cambodia Country Team, National Center for HIV/STD/and TB Prevention, Centers for Disease Control & Prevention, Cambodia-CDC AIDS Project Team, AmEmbassy Phnom Penh, Phnom Penh, Cambodia. Telephone: 011-855 23 217640. E-mail: jns1@cdc.gov.

Dated: August 14, 2002.

Sandra R. Manning,

CGFM, Director, Procurement & Grants Office, Centers for Disease Control & Prevention.

[FR Doc. 02-21251 Filed 8-20-02; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Potential Health Effects Involving Use of Perchloroethylene; Notice of Meeting

National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Potential Health Effects Involving Use of Perchloroethylene (PCE) in Dry-cleaning and Other Industries: Scientific Presentations and Information-gathering Meeting.

Time and Date: 9 a.m.-5 p.m., September 25, 2002.

Place: Alice Hamilton Building, Conference Room C, NIOSH, CDC, 5555 Ridge Avenue, Cincinnati, Ohio 45213.

Status: Forum will include scientists and representatives from various government agencies and independent groups, and is open to the public, limited only by the space available. The meeting room accommodates 80 people. Due to limited space, notification of intent to attend the meeting must be made with Judy Curless no later than September 13, 2002. Ms. Curless can be reached by telephone at 513/533-8314 or by e-mail jcc4@cdc.gov. Requests to attend will be accommodated on a first come basis.

Purpose: To discuss current research with PCE and identify partners for exchange of information and data on occupational exposure to PCE and potential health effects. A panel of invited participants will present data. Presentations and discussion will focus on health effects related to occupational exposures to PCE as well as data from studies of carcinogenicity and other effects in

animals. The public is invited to attend and will have the opportunity to provide comments.

Contact Person for General Information: Judy Curless, Education and Information Division, NIOSH, CDC, 4676 Columbia Parkway, MS C-32, Cincinnati, Ohio 45226, telephone 513/533-8314, fax 513/533-8230, e-mail jcc4@cdc.gov.

Contact Person for Technical Information: Thomas Lentz, Education and Information Division, NIOSH, CDC, 4676 Columbia Parkway, MS C-32, Cincinnati, Ohio 45226, telephone 513/533-8260, fax 513/533-8230, e-mail tbl7@cdc.gov.

Written research, data, or supporting materials to be considered in support of the information gathering effort should be submitted to the NIOSH Docket Office, ATTN: Diane Miller, Robert A. Taft Laboratories, M/S C-34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533-8450, fax 513/533-8285. Comments may also be submitted by e-mail to: NIOCDOCKET@CDC.GOV. E-mail attachments should be formatted as WordPerfect 6/7/8/9, or Microsoft Word. Comments should be submitted to NIOSH no later than November 15, 2002, and should reference docket number NIOSH-007 in the subject heading.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 15, 2002.

Joseph E. Salter,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02-21252 Filed 8-20-02; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Board on Radiation and Worker Health (ABRWH).

Time and Date: 1 p.m.-2 p.m., August 22, 2002.

Place: Teleconference call will originate at the Centers for Disease Control and Prevention, National Institutes for Occupational Safety and Health, Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the teleconference.

Status: Open to the public, teleconference access limited only by ports available.

Background: The Advisory Board on Radiation and Worker Health ("the Board") was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by Department of Health and Human Services (HHS), advice on methods of dose reconstruction which have been promulgated as an interim final rule, evaluation of the validity and quality of dose reconstructions conducted by the National Institute for Occupational Safety and Health (NIOSH) for qualified cancer claimants, and advice on the addition of classes of workers to the Special Exposure Cohort.

In December 2000, the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the Centers for Disease Control and Prevention (CDC). NIOSH implements this responsibility for CDC. The charter was signed on August 3, 2001 and in November 2001, the President completed the appointment of an initial roster of 10 Board members. The initial tasks of the Board have been to review and provide advice on the proposed and interim rules of HHS.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: Agenda for this meeting will focus on the Board finalizing comments on the Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000; proposed rule 42 CFR part 83. The period for comment closes on August 26, 2002, and the Advisory Board on Radiation and Worker Health is required to comment as mandated by the Energy Employees Occupational Illness Compensation Program Act of 2000.

Agenda items are subject to change as priorities dictate.

This request has been submitted late as this conference call was scheduled on August 15, 2002. This conference call cannot be delayed as the open comment period closes on August 26, 2002; two business days after this conference call takes place.

SUPPLEMENTARY INFORMATION: This conference call is scheduled for 1:00 p.m. Eastern Standard Time. To access the

teleconference you must dial 1/800-311-3437. To be automatically connected to the call, you will need to provide the operator with the participant code "984100" and you will be connected to the call.

Contact Person for More Information: Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/841-4498, fax 513/458-7125.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 16, 2002.

Joseph E. Salter,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02-21400 Filed 8-20-02; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Sanitation Inspections of Cruise Ships

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces fees for vessel sanitation inspections for fiscal year 2003 (October 1, 2002, through September 30, 2003).

EFFECTIVE DATE: October 1, 2002.

FOR FURTHER INFORMATION CONTACT:

David L. Forney, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop F-16, Atlanta, Georgia 30341-3724, telephone (770) 488-7333, e-mail: Dforney@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Background

The fee schedule for sanitation inspections of passenger cruise ships currently inspected under the Vessel Sanitation Program (VSP) was first published in the **Federal Register** on November 24, 1987 (52 FR 45019), and CDC began collecting fees on March 1, 1988. Since then, CDC has published the fee schedule annually. This notice announces fees effective October 1, 2002.

The formula used to determine the fees is as follows:

$$\text{Average cost per inspection} = \frac{\text{Total cost of VSP}}{\text{Weighted Number of annual inspections}}$$

The average cost per inspection is multiplied by a size/cost factor to determine the fee for vessels in each size category. The size/cost factor was established in the proposed fee schedule published in the **Federal Register** on July 17, 1987 (52 FR 27060), and revised in a schedule published in the **Federal Register** on November 28, 1989 (54 FR 48942). The revised size/cost factor is presented in Appendix A.

Fee

The fee schedule is presented in Appendix A and will be effective October 1, 2002, through September 30, 2003. This fee schedule represents a 4.2 percent decrease over the current fee schedule, which became effective October 1, 2001. If travel expenses continue to increase, it may be necessary to readjust the fees before September 30, 2003, because travel comprises a sizable portion of the program's costs. If such a readjustment in the fee schedule is necessary, a notice will be published in the **Federal Register** 30 days before the effective date.

Applicability

The fees will be applicable to all passenger cruise vessels for which inspections are conducted as part of CDC's VSP.

Dated: August 15, 2002.

James D. Seligman,

*Associate Director for Program Services,
Centers for Disease Control and Prevention.*

APPENDIX

Appendix A

SIZE/COST FACTOR

Vessel size	GRT ¹	Average cost
Extra Small	<3,001	0.25
Small	3,001–15,001	0.50
Medium	15,000–30,000	1.00
Large	30,001–60,000	1.50
Extra Large	>60,000	2.00

¹GRT—Gross register tonnage in cubic feet, as shown in *Lloyd's Register of Shipping*.

FEE SCHEDULE OCTOBER 1, 2002– SEPTEMBER 30, 2003

Vessel size	GRT ¹	Fee (\$U.S.)
Extra small	<3,001	1,150

FEE SCHEDULE OCTOBER 1, 2002– SEPTEMBER 30, 2003—Continued

Vessel size	GRT ¹	Fee (\$U.S.)
Small	3,001–15,000	2,300
Medium	15,001–30,000	4,600
Large	30,001–60,000	6,900
Extra large	>60,000	9,200

Note: Inspections and reinspections involve the same procedure, require the same amount of time, and are, therefore, charged at the same rate.

[FR Doc. 02–21249 Filed 8–20–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0350]

Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Handling and Retention of Bioavailability and Bioequivalence Testing Samples.” Inspection of clinical and analytical sites that perform bioavailability (BA) and bioequivalence (BE) studies frequently reveals the absence of reserve samples at the testing facilities where the studies are conducted. The draft guidance is intended to clarify how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain reserve samples.

EFFECTIVE DATE: Submit written or electronic comments on the draft guidance by September 20, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Martin Yau, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5458.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Handling and Retention of Bioavailability and Bioequivalence Testing Samples.” Following the generic drug crisis in the 1980s, FDA issued regulations to deter possible bias and fraud in BA and BE testing by study sponsors and/or drug manufacturers (58 FR 25918, April 28, 1993). In the preamble of the final rule, the agency stated that the study sponsor should not separate out the reserve samples of the test article and reference standard prior to sending the drug product to the testing facility. This is to ensure that the reserve samples are in fact representative of the same batches provided by the study sponsor for the testing. FDA's Division of Scientific Investigations and field investigators from the Office of Regulatory Affairs conduct inspections of clinical and analytical sites that perform BA and BE studies for sponsors and/or drug manufacturers seeking approval of generic and new drug products. A frequent finding from these inspections is the absence of reserve samples at the testing facility. This draft guidance clarifies the responsibilities of the involved parties for retention of samples used in BA and BE studies. It includes recommendations for sampling techniques and responsibilities in various study settings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on retention of BA and BE testing samples. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An

alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 13, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02-21262 Filed 8-20-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0337]

Draft Guidance for Industry on Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation." This guidance provides recommendations to applicants on the chemistry, manufacturing, and controls (CMC); human pharmacokinetics and bioavailability; and labeling documentation for liposome drug products submitted in new drug applications (NDAs).

DATES: Submit written or electronic comments on the draft guidance by

November 19, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Liang Zhou, Center for Drug Evaluation and Research (HFD-180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7471.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation."

Liposome drug products are defined as drug products containing drug substances (active pharmaceutical ingredients) encapsulated in liposomes. A liposome is a microvesicle composed of a bilayer of lipid amphipathic molecules enclosing an aqueous compartment. Liposome drug products are formed when a liposome is used to encapsulate a drug substance within the lipid bilayer or in the interior aqueous space of the liposome. A drug substance in a liposome formulation is intended to exhibit a different pharmacokinetic and/or tissue distribution (PK/TD) profile from the same drug substance (or active moiety) in a nonliposomal formulation given by the same route of administration. The complete characterization of the PK/TD profile of a new liposome drug product is essential to establish the safe and effective dosing regimen of the product.

The guidance provides recommendations to applicants on the CMC, human pharmacokinetics and bioavailability, and labeling documentation for liposome drug products submitted in NDAs. The guidance does not provide recommendations on: (1) Clinical

efficacy and safety studies, (2) nonclinical pharmacology and/or toxicology studies, (3) bioequivalence studies or those to document sameness, (4) liposomal formulations of vaccine adjuvants or biologics, or (5) drug-lipid complexes.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on liposome drug products: CMC, human pharmacokinetics and bioavailability, and labeling documentation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 13, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02-21263 Filed 8-20-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Rural Assistance Center

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration announces up to \$600,000 in FY 2002 funds is available to fund a single competitive

cooperative agreement to support the development of a Rural Assistance Center (RAC) demonstration project. The RAC will assist rural communities and individual rural citizens in building and sustaining high-quality rural health care delivery systems.

Eligibility is open to any public or private entity. Faith-based organizations are eligible to apply for these funds. Awards will be made under the program authority of Section 301 of the Public Health Service Act. Funds for this award were appropriated under Public Law 107-116. The award will be for a period of three years. Additional funding of up to \$600,000 annually in the second or third years is contingent on the availability of funds and grantee performance.

DATES: Applicants for this program are requested to notify the Office of Rural Health Policy by September 1, 2002. Notification of intent to apply can be made in one of three ways: telephone: 301-443-0835; e-mail shirsch@hrsa.gov; mail, Office of Rural Health Policy, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857. The deadline for receipt of grant applications is September 16, 2002. Applications will be considered on time if received on or before this date.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1-877-477-2123 (1-877-HRSA-123) beginning August 16, 2002, or register on-line at: <http://www.hrsa.gov/>, or by accessing http://www.hrsa.gov/g_order3.htm directly. This program uses the standard Form PHS 5161-1 (rev. 7/00) for applications (approved under OMB No. 0920-0428). Applicants must use the Catalog of Federal Domestic Assistance (CFDA) number 93.223 when requesting application materials. The CFDA is a Government wide compendium of enumerated Federal programs, projects, services, and activities that provide assistance. An original and paper copies of applications should be mailed to: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg MD, telephone: 1-877-HRSA-123 (477-2123), E-mail: hrsagac@hrsa.gov.

This application guidance and the required form for the Rural Assistance Center Program may also be downloaded in either Microsoft Word or Adobe Acrobat format (.pdf) from the ORHP Homepage at <http://www.ruralhealth.hrsa.gov>. Please contact Steve Hirsch at 301-443-0835 or shirsch@hrsa.gov if you need technical assistance in accessing the ORHP Home Page via the Internet.

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

For the 65 million people living in rural America, the U.S. Department of Health and Human Services' mission to protect health and to provide assistance for those in need is especially relevant. Health care and social service programs in rural communities provide needed support of communities' well-being and represent a significant segment of the local economies. These programs, however, frequently lack adequate funds, personnel and support network.

For more than a decade, the Office of Rural Health Policy has supported activities that assist states, localities and rural citizens as they work to build and sustain high-quality rural health care delivery systems. One component of that support has been the Rural Information Center Health Service (RICHS). The intent of the RAC is to demonstrate that this activity can be expanded and enhanced to better serve rural communities by identifying private and public resources, collecting and sharing information about models that work, and serving as a technical resource for a wide range of health and social service issues.

In July of 2001, Secretary of Health and Human Services Tommy G. Thompson created a rural task force to assess how the Department serves rural communities. Among the key findings of this year-long initiative is that DHHS operates more than 220 discrete programs that affect rural communities. As part of the rural initiative, the Department's Rural Task Force also collected more than 450 public comments on a variety of issues affecting rural communities. One of the key themes that emerged from these public comments is the need to reach out to rural communities and help them identify how best to access the broad range of health and social services programs that are available to rural communities.

The Rural Assistance Center will serve as a focal point of information about the broad range of public and private opportunities that are available to support rural communities. The RAC will help rural communities navigate these opportunities, identify successful state and community models and provide links to existing private and public resources that support rural health care and social service delivery. This will, in turn, help rural communities build and enhance their rural services and strengthen their communities.

Authorization: Section 301 of the Public Health Service Act, 42 U.S.C. 241.

Purpose

The purpose of this cooperative agreement is to assist rural communities in developing and sustaining high-quality rural health care and social service delivery systems through an integrated assistance center. Specifically, through this cooperative agreement the RAC will:

- (1) Serve as a support to rural communities and rural citizens to identify available programs for improving the ability of rural communities to provide high-quality health care and social services.
- (2) Identify and synthesize information about the availability of existing private and public resources for enhancing rural health care and social service delivery.
- (3) Identify and disseminate information about models that work in rural communities that have been able to sustain, enhance and improve their local health care and social service delivery systems.
- (4) Promote collaboration among DHHS programs that serve rural communities to increase effectiveness and reduce duplication of effort.

Eligibility

Under section 301 of the Public Health Service Act, any public or private entity is eligible to apply. Under the President's initiative, community-based and faith-based organizations that are otherwise eligible and believe they can contribute to HRSA's program objectives are encouraged to consider this initiative.

Funding Levels/Project Periods

The administrative and funding instrument to be used for the RAC will be a cooperative agreement, in which substantial ORHP policy expertise and/or programmatic involvement with the awardee is anticipated during the performance of the project. There is no requirement for matching funds with this program. Under the terms of this cooperative agreement, in addition to the required monitoring and technical assistance, Federal responsibilities will include:

- (1) Participation in meetings conducted during the period of the cooperative agreement.
- (2) Ongoing review of activities and procedures to be established and implemented.
- (3) Review of project information prior to dissemination.

(4) Review of information on project activities.

(5) Assistance with the establishment of contacts with Federal and State agencies, grant projects and other contacts that may be relevant to the project's mission and referrals to these agencies.

One project will be approved for three years. Up to \$600,000 in fiscal year 2002 funds will be used to fund the first year. Additional funding of up to \$600,000 annually in years two and three will be contingent on the availability of funds and grantee performance.

Review Criteria

Applications that are complete and responsive to the guidance will be evaluated by an objective review panel specifically convened for this solicitation and in accordance with HRSA grants management policies and procedures.

Applications will be reviewed using the following criteria:

1. Knowledge and Understanding of the Issues relating to Rural Health and Rural Social Services (Weight: 20%) and the Challenges Facing Providers and Beneficiaries in Rural Areas

- The degree of understanding of the evolution of rural health and social services and the historical challenges facing rural communities in terms of resources and demographics (including populations experiencing cultural and linguistic barriers to care).

- The degree of thoroughness in describing how the RAC will address information gaps for rural communities.

- The extent of applicant knowledge of rural health and social service issues.

- The extent of applicant knowledge of the individuals and organizations involved in the rural health and social services.

2. Soundness and Adequacy of Project Plan (Weight: 30%)

- The extent to which the project objectives address the program purpose and are measurable, time-framed, and appropriate in relation to both the program requirements and identified needs.

- The degree to which the program areas outlined in the grant guidance have been addressed, prioritized and justified.

- The quality and feasibility of the project plan or methodology and its relation to the project's goals and objectives.

- The extent to which the proposed approach identifies the resources that will be used to implement the strategies.
- The degree to which the approaches are technically sound and appropriate to the project goals and objectives.

3. Soundness of Implementation Plan (Weight: 10%)

- The soundness of the plan for creating and implementing the RAC.

- The extent to which the applicant describes how the project staff will determine the degree to which proposed activities are being successfully conducted and completed, based on the objectives outlined.

4. Applicant's Capability and Capacity (Weight: 30%)

- The extent to which the applicant has demonstrated expertise and its capability to oversee and successfully carry out the project.

- Evidence that a sufficient number of project personnel and resources are proposed. Biographical sketches/curricula vitae document education, skills and experience that are relevant and necessary for the proposed project.

5. Appropriateness of Budget (Weight: 10%)

- The extent to which the proposed budget is realistic, adequately justified, and consistent with the proposed project plan.

- The extent to which the costs of administration and monitoring/evaluation are reasonable and proportionate to the costs of service provision.

- The degree to which the costs of the proposed project are economical in relation to the proposed service utilization.

Additional criteria may be used in the review of applications for this competition. Any such criteria will be identified in the program guidance included in the application kit.

Applicants should pay strict attention to addressing these criteria, in addition to those referenced above.

This program is not subject to the provision of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). This program is also not subject to the Public Health Systems Reporting Requirements.

Paperwork Reduction Act

OMB approval for any data collection in connection with this cooperative agreement will be sought, as required under the Paperwork Reduction Act of 1995.

Dated: August 15, 2002.

Elizabeth M. Duke,
Administrator.

[FR Doc. 02-21340 Filed 8-20-02; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Development of High-Yield Technologies for Isolating Exfoliated Cells in Body Fluids.

Dated: September 18, 2002.

Time: 8 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Boulevard, Executive Plaza North, Room H, Rockville, MD 20852.

Contact Person: Kenneth L. Bielat, PhD, Scientific Review Administrator, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892, (301) 496-7576, bielatk@mail.nih.gov.

Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-21234 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Phase I & Phase II Clinical Studies of Chemopreventive Agents.

Date: September 30–October 1, 2002.

Time: 8 AM to 5 PM.

Agenda: To review and evaluate contract proposals.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Lalita D Palekar, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institute of Health, 6116 Executive Boulevard, Room 8105, Bethesda, MD 20892–7405, (301) 496–7575.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–21244 Filed 8–20–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, “Autoimmunity: Mechanisms of Unresponsiveness”.

Date: September 11, 2002.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: 6700B Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Geetha P. Bansal, PhD, Scientific Review Administrator, NIAID/DEA, Scientific Review Program, Room 2217, 6700B Rockledge Drive MSC–7616, Bethesda, MD 20892–7616, 301–496–2550, gbansal@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–21232 Filed 8–20–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, “Imaging Inflammation in Autoimmune Disease”.

Date: September 10, 2002.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: 6700–B Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Geetha P. Bansal, PhD, Scientific Review Administrator, NIAID/DEA, Scientific Review Program, Room 2217, 6700B Rockledge Drive MSC–7616, Bethesda, MD 20892–7616, 301–496–2550, gbansal@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–21233 Filed 8–20–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Neurological Disorders and Stroke, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

Date: September 22–24, 2002.

Closed: September 22, 2002, 7 PM to 10 PM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.
Open: September 23, 2002, 8:30 AM to 9:25 AM.

Agenda: To discuss program planning and program accomplishments.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852.

Closed: September 23, 2002, 9:25 AM to 9:55 AM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Open: September 23, 2002, 9:55 AM to 10:35 AM.

Agenda: To discuss program planning and program accomplishments.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Closed: September 23, 2002, 10:35 AM to 11:05 AM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Open: September 23, 2002, 11:05 AM to 12:00 PM.

Agenda: To discuss program planning and program accomplishments.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Closed: September 23, 2002, 12 PM to 1:20 PM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Open: September 23, 2002, 1:20 PM to 2 PM.

Agenda: To discuss program planning and program accomplishments.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Closed: September 23, 2002, 2 PM to 2:30 PM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Open: September 23, 2002, 2:30 PM to 3:10 PM.

Agenda: To discuss program planning and program accomplishments.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Closed: September 23, 2002, 3:10 PM to 3:30 PM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Closed: September 23, 2002, 4:30 PM to 7 PM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Closed: September 24, 2002, 8:30 AM to Adjournment.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Story C. Landis, PhD, Director, Division of Intramural Research, NINDS, National Institutes of Health, Building 36, Room 5A05, Bethesda, MD 20892, 301-435-2232.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-21236 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel. K23s, K24s, & K25s.

Date: September 11, 2002.

Time: 1 pm to 2 pm.

Agenda: To review and evaluate grant applications.

Place: 1 Democracy, 6701 Democracy Blvd., Suite 707 MSC 4870, Bethesda, MD 20892-4870, (Telephone Conference Call).

Contact Person: Tracy A. Shahan, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Disease, Natcher Building, MSC 6500, 45 Center Drive, 5AS-25H, Bethesda, MD 20892, (301) 594-4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-21237 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel. Clinical Trial Planning Grants.

Date: September 10, 2002.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Richard J Bartlett, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892, (301) 594-4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-21238 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussion could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel. Basic and Applied Stem Cell Research for Arthritis and Musculoskeletal Disease.

Date: August 30, 2002.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20853.

Contact Person: John R. Lyman-grover, PHD, Scientific Review Administrator, National Institutes of Health, NIAMS, 6701 Democracy Plaza, Bethesda, MD 20892, 301-594-4952.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-21239 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Parkinson's Disease Gene Therapy Study Group.

Date: August 18-19, 2002.¹

Time: 7:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, 4300 Military Road, NW., Chevy Chase, MD 20015.

Contact Person: W. Ernest Lyons, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-4056.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, NeuroAIDS Studies.

Date: August 21-22, 2002.

Time: 7:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Grand Hotel, 2350 M Street, NW., Washington, DC 20037.

Contact Person: Andrea Sawczuk, DDS, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-0660.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854,

¹ Editorial note: This document was received at the Office of the Federal Register on August 16, 2002.

Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02-21240 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, ZAA1 BB (29) R21, Application Review Meeting.

Date: August 16, 2002.¹

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Willco Building, Suite 409, 6000 Executive Boulevard, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Elsie D. Taylor, Scientific Review Administrator, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Blvd., Bethesda, MD 20892-7003, 301-443-9787, etaylor@niaaa.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

¹ Editorial Note: This document was received at the Office of the Federal Register on August 16, 2002.

Dated: August 13, 2002.

LaVerne Y. Stringfield,
Director, Office of Federal Advisory
Committee Policy.

[FR Doc. 02-21245 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 02-78, Review of R01 and R21 Grants.

Date: August 19-20, 2002.¹

Time: 8:30 AM to 12 PM.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Anna Sandberg, MPH, DRPH, Scientific Review Administrator, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN44F, Bethesda, MD 20892, (301) 594-3089.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 02-79, Review of R01 Grants.

Date: August 20, 2002.

Time: 1:30 PM to 3:30 PM.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Anna Sandberg, MPH, DRPH, Scientific Review Administrator,

National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN44F, Bethesda, MD 20892, (301) 594-3089.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 02-95, Review of R13 Grants.

Date: September 10, 2002.

Time: 3 PM to 5 PM.

Agenda: To review and evaluate grant applications and/or proposals.

Place: 45 Center Drive, Natcher Bldg., Conf. Rms. A & D, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: H. George Hausch, PHD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594-2372.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 02-94, Review of R25 Grants.

Date: September 17, 2002.

Time: 1 PM to 3 PM.

Agenda: To review and evaluate grant applications.

Place: 45 Center Drive, Natcher Building, Conference Room E1/2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: H. George Hausch, PHD, Acting Director, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594-2372.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: August 14, 2002.

LaVerne Y. Stringfield,
Director, Office of Federal Advisory
Committee Policy.

[FR Doc. 02-21247 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biomedical Library and Informatics Review Committee.

Date: November 7-8, 2002.

Time: November 7, 2002, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Library of Medicine, Board Room, Room 2E17, Bldg. 38, 8600 Rockville Pike, Bethesda, MD 20892.

Time: November 8, 2002, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Library of Medicine, Board Room, Room 2E17, Bldg. 38, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Merlyn M. Rodrigues, MD, PhD, Medical Officer/SRA, National Library of Medicine, Extramural Programs, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,
Director, Office of Federal Advisory
Committee Policy.

[FR Doc. 02-21235 Filed 8-20-02; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Library of Medicine.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL LIBRARY OF MEDICINE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Library of Medicine, Board of Scientific Counselors, National Center for Biotechnology Information, National Library of Medicine.

¹ Editorial Note: This document was received at the Office of the Federal Register on August 16, 2002.

Date: October 7–8, 2002.

Time: October 7, 2002, 7 PM to 10 PM.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Library of Medicine, Board Room Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Time: October 8, 2002, 8:30 AM to 2:00 PM.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Library of Medicine, Board Room Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: David J. Lipman, MD, Director, Natl Ctr for Biotechnology Information, National Library of Medicine, Department of Health and Human Services, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: August 14, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–21241 Filed 8–20–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel, Publication Grants.

Date: November 15, 2002.

Time: 8:30 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Merlyn M. Rodrigues, MD, PhD, Medical Officer/SRA, National Library of Medicine, Extramural Programs, 6705

Rockledge Drive, Suite 301, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–21242 Filed 8–20–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the PubMed Central National Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: PubMed Central National Advisory Committee.

Date: November 4, 2002.

Time: 9:30 a.m. to 4 p.m.

Agenda: Review and Analysis of Systems.

Place: Library of Medicine, Board Room, Room 2E17, Bldg. 38, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: David J. Lipman, MD, Director, Natl Ctr for Biotechnology Information, National Library of Medicine, Department of Health and Human Services, Bethesda, MD 20894.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: <http://www.pubmedcentral.nih.gov/about/nac/html>, where an agenda and any additional information for the meeting will be posed when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–21243 Filed 8–20–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussion could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which could constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Vision Bioengineering Research Grants and Partnership.

Date: August 23, 2002.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Peter Lyster, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7806, Bethesda, MD 20892, (301) 435–1256, lysterp@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393–93, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–21246 Filed 8–20–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**[Docket No. FR-4734-N-33]****Notice of Submission of Proposed Information Collection to OMB; Single Family Premium Collection Subsystem-Periodic (SFPCS-P)****AGENCY:** Office of the Chief Information Officer, HUD.**ACTION:** Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* September 20, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0536) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235,

New Executive Office Building, Washington, DC 20503; Fax number (202) 395-6974; e-mail Lauren_Wittenberg@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be

affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department. This Notice also lists the following information:

Title of Proposal: Single Family Premium Collection Subsystem-Periodic (9SFPCS-P)

OMB Approval Number: 2502-0536.

Form Numbers: None.

Description of the Need For the Information and Its Proposed Use: Mortgagees are required to submit mortgage insurance premium data on a monthly basis.

Respondents: Business or other for-profit, State, Local or Tribal Government.

Frequency of Submission: On occasion.

	Number of respondents	Annual responses	x	Hours per response	=	Burden hours
Reporting Burden	1,800	12		1		21,600

Total Estimated Burden Hours: 21,600.

Status: Extension of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: August 13, 2002.

Wayne Eddins,

*Departmental Reports Management Officer,
Office of the Chief Information Officer.*

[FR Doc. 02-21229 Filed 8-20-02; 8:45 am]

BILLING CODE 4210-72-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**[Docket No. FR-4734-N-34]****Mortgage Insurance for Cooperative and Condominium Housing; Notice of Submission of Proposed Information Collection to OMB****AGENCY:** Office of the Chief Information Officer, HUD.**ACTION:** Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of

Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* September 20, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0141) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395-6974; e-mail Lauren_Wittenberg@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including the number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Mortgage Insurance for Cooperative and Condominium Housing.

OMB Approval Number: 2502-0141.

Form Numbers: HUD-93201.

Description of the Need for the Information and Its Proposed Use: Project Information is analyzed to determine whether a cooperative or condominium project is eligible for mortgage insurance.

Respondents: Business or other for-profit, not-for-profit institutions.

Frequency of Submission: On occasion.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden	15	1		6		91

Total Estimated Burden Hours: 91.
Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: August 13, 2002.

Wayne Eddins,

*Departmental Reports Management Officer,
Office of the Chief Information Officer.*

[FR Doc. 02-21230 Filed 8-20-02; 8:45 am]

BILLING CODE 4210-72-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Intent to Prepare a Comprehensive Conservation Plan and Associated Environmental Impact Statement for the Desert National Wildlife Refuge Complex

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent to prepare a Comprehensive Conservation Plan and Associated Environmental Impact Statement for the Desert National Wildlife Refuge Complex.

SUMMARY: This notice advises the public that the U.S. Fish and Wildlife Service (Service) intends to gather information necessary to prepare a Comprehensive Conservation Plan (CCP) and an associated Environmental Impact Statement (EIS) for the Desert National Wildlife Refuge Complex. The Desert National Wildlife Refuge Complex is composed of Ash Meadows National Wildlife Refuge, Desert National Wildlife Range, Moapa Valley National Wildlife Refuge and Pahrangat National Wildlife Refuge located in Clark, Lincoln and Nye Counties, Nevada. A Wilderness Review of Desert National Wildlife Range will also be completed concurrently in accordance with the Wilderness Act of 1964, as amended, and Refuge Planning Policy

602 FW Chapters 1, 2, and 3. The Service is furnishing this notice in compliance with our National Wildlife Refuge Planning Policy and the National Environmental Policy Act of 1969, as amended (NEPA), and implementing regulations, to advise other agencies, Tribal Governments, and the public of our intentions, and to obtain suggestions and information on the scope of issues and alternatives to include in the CCP and the environmental document.

DATES: A series of public scoping meetings will be held on September 16 through September 19 at the following locations:

Date	Time	Location
Sept. 16, 2002	7-9 pm	Moapa Community Center, Moapa Valley, NV.
Sept. 17, 2002	7-9 pm	Fish and Wildlife Service Office, Las Vegas, NV.
Sept. 18, 2002	4-6 pm	Amargosa Valley Multi-purpose Building, Amargosa Valley, NV.
Sept. 18, 2002	7-9 pm	Bob Ruud Community Center, Pahrump, NV.
Sept. 19, 2002	7-9 pm	Alamo Annex Building, Alamo, NV.

Interested persons are encouraged to attend these meetings to identify issues, concerns, and opportunities to be addressed in the CCP. For directions to the meetings, please contact us at the phone number listed below. To ensure that the Service has adequate time to evaluate and incorporate suggestions and other input into the planning process, comments should be received within 60 days from the date of this notice.

ADDRESSES: Address comments and requests to be put on the mailing list, receive more information, or receive a copy of the most recent planning update to: Project Leader, U.S. Fish and Wildlife Service, 4701 North Torrey Pines, Las Vegas, NV 89130 or call the

Complex at (702) 515-5450. Submit faxes to (702) 515-5460. If you choose to submit comments via electronic mail, visit <http://desertcomplex.fws.gov> and use the "Guest Mailbox" provided at that site. More information on the CCP process is also available at the above internet site by selecting the "CCP Planning Update" link.

FOR FURTHER INFORMATION CONTACT: Richard Birger, Project Leader, at the address and phone number above.

SUPPLEMENTARY INFORMATION:

Ash Meadows National Wildlife Refuge

Established in 1984 under the authority of the Endangered Species Act of 1973, as amended, the Refuge comprises 23,000 acres of spring fed

wetlands, mesquite bosques, and desert uplands that provide habitat for at least 24 plants and animal species found nowhere else in the world. The primary purpose of the Refuge is to provide for the protection and recovery of endangered fish and plants, such as Devil's Hole, Ash Meadows Amargosa, and Warm Springs pupfish, Ash Meadows speckled dace, Ash Meadows milk-vetch, spring-loving centaury plant, Ash Meadows sunray, Ash Meadows ivesia, Ash Meadows gumplant, and Ash Meadows blazing star. The Amargosa Pupfish Station, located within the Refuge, is home to a vertebrate species that may have one of the most restricted habitats on the planet. The most striking feature of the

Refuge is the more than 30 spring-fed pools and streams that contrast sharply with the arid desert that surround them.

Desert National Wildlife Range

The Refuge, established in 1936 by Executive Order No. 7373 for the protection, preservation and management of desert bighorn sheep, as well as other forms of native flora and fauna occurring on the Refuge, encompasses 1.5 million acres of the diverse Mojave Desert in southern Nevada. It is the largest National Wildlife Refuge in the lower 48 states.

The Military Lands Withdrawal Act of 1999, Pub. L. No. 106-65, authorized the withdrawal of 2,919,890 acres of public lands in Clark, Nye, and Lincoln Counties, Nevada from all forms of appropriation under the public lands laws (including the mining laws and the mineral leasing and the geothermal leasing laws). These withdrawn lands were reserved for use by the Secretary of the Air Force for military testing, training and other defense-related purposes. During the period of withdrawal, the Act provides that the lands within the Desert National Wildlife Range will be managed by the Secretary of the Interior pursuant to the National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd, *et seq.*) and other laws applicable to the National Wildlife Refuge System. Pursuant to a Memorandum of Understanding with the Secretary of the Air Force, The Secretary of the Interior is to manage withdrawn lands for the purposes for which the Refuge was established and to support current and future military aviation training.

Moapa Valley National Wildlife Refuge

The Refuge was established September 10, 1979, under the authority of the Endangered Species Act of 1969, as amended, to secure habitat for the endangered Moapa dace. The Refuge is located on 106 acres in northeastern Clark County. Due to its small size, fragile habitats, on-going habitat restoration work, and unsafe structures, the Refuge is currently closed to the general public.

Pahranagat National Wildlife Refuge

The Refuge was established in 1963, under the authority of the Migratory Bird Conservation Act, as amended, to provide protection and habitat for migrating birds in the Pahranagat Valley. The 5,382 acre refuge consists of marshes, meadows, lakes, and upland desert habitat. It provides nesting, resting, and feeding areas for ducks, geese, swans, and other birds.

Background and Planning Process

The National Wildlife Refuge System Administration Act of 1966, as amended, requires the Service to manage all lands within the National Wildlife Refuge System in accordance with an approved CCP (16 U.S.C. 668dd(e)). The CCP will guide wildlife, habitat, and public use management decisions and identify refuge goals, long-range objectives, and strategies for achieving Refuge purposes. Public input into this planning process is encouraged. The CCP will provide other agencies and the public with a clear understanding of the desired conditions for the Refuges and how the Service will implement management strategies over the next 15 years. Until the CCP is completed, Refuge management will continue to be guided by refuge purposes, federal legislation regarding management of national wildlife refuges, and other legal, regulatory and policy guidance.

Comments and concerns received will be used to develop goals, key issues and management strategies, and draft alternatives. Additional opportunities for public participation will occur throughout the CCP process, which is expected to be completed by 2005. Input from interested federal, state, and local agencies, Native American tribes, organizations and individuals is encouraged.

During development of the CCP, we will comply with the provisions of NEPA through concurrent preparation of an EIS that will accompany the CCP. The draft EIS will contain a No Action Alternative, a proposed action alternative, and potentially other alternatives. The alternatives will be used to define management options and compare their effects. The potential environmental impacts of each alternative will be analyzed in the draft EIS. A range of alternatives (and their effects on the biological resources and on the local communities) that address the issues and the management strategies associated with the issues will be evaluated in the EIS.

We are required by Service policy to complete a wilderness review of Service managed lands to determine if any lands are suitable for inclusion in the National Wilderness Preservation System. The wilderness review will be integrated into the CCP/EIS process including identification of areas that meet the minimum wilderness criteria; evaluation of the wilderness suitability of alternatives; and documentation of recommendations. Wilderness designation requires Congressional legislation. The last step, if appropriate,

would consist of forwarding any suitable recommendations from the Director of the Service, through the Secretary of the Interior and the President, to Congress in a Wilderness Study Report.

Conclusion

With the publication of this notice, the public is encouraged to help identify potential issues, management actions and concerns; significant problems or impacts; and opportunities to resolve them. The public scoping period will continue for 60 days from the date of this notice. However, the Service will accept comments throughout the planning process.

All comments received from individuals on environmental impact statements become part of the official public record. Requests for such comments will be handled in accordance with the Freedom of Information Act, the Council on Environmental Quality's NEPA regulations [40CFR1506.6(f)] and other Service and Departmental policy and procedures.

The environmental review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), NEPA Regulations (40 CFR 1500-1508), other appropriate Federal laws and regulations, Executive Order 12996, and Service policies and procedures for compliance with those regulations.

Dated: August 7, 2002.

Ken McDermond,

Acting Manager, California/Nevada Operations Office, Sacramento, California.
[FR Doc. 02-20699 Filed 8-20-02; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Meeting of the Klamath Fisheries Management Council

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the Klamath Fishery Management Council, established under the authority of the Klamath River Basin Fishery Resources Restoration Act (16 U.S.C. 460ss *et seq.*). The Klamath Fishery Management Council makes recommendations to agencies that regulate harvest of anadromous fish in

the Klamath River Basin. The objectives of this meeting are to hear technical reports, discuss management of Klamath Basin spring Chinook, review the 2002 fisheries, and discuss fall Chinook management and allocation issues related to the 2003 season. The meeting is open to the public.

DATES: The Klamath Fishery Management Council will meet from 10 a.m. to 5 p.m. on Wednesday, October 9, 2002, from 8 a.m. to 5 p.m. on Thursday, October 10, 2002, and from 8 a.m. to 1 p.m. on Friday, October 11, 2002.

ADDRESSES: The meeting will be held at the U.S. Fish and Wildlife Service, Yreka Fish and Wildlife Office, 1829 South Oregon Street, Yreka, California.

FOR FURTHER INFORMATION CONTACT: Phil Detrich, Project Leader, U.S. Fish and Wildlife Service; 1829 South Oregon Street; Yreka, California 96097; telephone (530) 842-5763.

SUPPLEMENTARY INFORMATION: For background information on the Klamath Fishery Management Council, please refer to the notice of their initial meeting that appeared in the **Federal Register** on July 8, 1987 (52 FR 25639).

Dated: August 14, 2002.

John Engbring,

Acting Manager, California/Nevada Operations Office, Sacramento, California.
[FR Doc. 02-21253 Filed 8-20-02; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Notice of meeting.

California Bay-Delta Public Advisory Committee Public Meeting

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the California Bay-Delta Public Advisory Committee will meet on September 19, 2002. The agenda for the Committee meeting will include reports from subcommittees, discussions on future governance, workplans and budgets, and water operations, regional reports, and implementation of the CALFED Bay-Delta Program with State and Federal officials.

DATES: The meeting will be held Thursday, September 19, 2002 from 9 a.m. to 4 p.m. If reasonable accommodation is needed due to a disability, please contact Pauline Nevins at (916) 657-2666 or TDD (800) 735-

2929 at least 1 week prior to the meeting.

ADDRESSES: The meeting will be held at the Metropolitan Water District of Southern California located at 700 North Alameda Street, Room 2-456, Los Angeles, California.

FOR FURTHER INFORMATION CONTACT: Eugenia Laychak, CALFED Bay Delta Program, at (916) 654-4214, or Diane Buzzard, U.S. Bureau of Reclamation, at (916) 978-5022.

SUPPLEMENTARY INFORMATION: The Committee was established to provide assistance and recommendations to Secretary of the Interior Gale Norton and California Governor Gray Davis on implementation of the CALFED Bay-Delta Program. The Committee will advise on annual priorities, integration of the eleven Program elements, and overall balancing of the four Program objectives of ecosystem restoration, water quality, levee system integrity, and water supply reliability. The Program is a consortium of 23 State and Federal agencies with the mission to develop and implement a long-term comprehensive plan that will restore ecological health and improve water management for beneficial uses of the San Francisco/Sacramento and San Joaquin Bay Delta.

Committee and meeting materials will be available on the CALFED Bay-Delta Web site: <http://calfed.ca.gov> and at the meeting. This meeting is open to the public. Oral comments will be accepted from members of the public at the meeting and will be limited to 3-5 minutes.

(Authority: The Committee was established pursuant to the Department of the Interior's authority to implement the Fish and Wildlife Coordination Act, 16 U.S.C. 661 *et seq.*, the Endangered Species Act, 16 U.S.C. 1531 *et seq.*, and the Reclamation Act of 1902, 43 U.S.C. 371 *et seq.*, and the acts amendatory thereof or supplementary thereto, all collectively referred to as the Federal Reclamation laws, and in particular, the Central Valley Project Improvement Act, Title 34 of Pub. L. 102-575.)

Dated: August 6, 2002.

Fredrick W. Breitenbach,

Acting Special Projects Officer, Mid-Pacific Region.

[FR Doc. 02-21250 Filed 8-20-02; 8:45 am]

BILLING CODE 4310-MN-M

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day notice of information collection under review: reinstatement, with change, of a previously approved collection for which approval has expired; Budget Detail Worksheet.

The Department of Justice (DOJ), Office of Justice Programs has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 67, Number 99, page 36023 on May 22, 2002, allowing for a 60 day comment period. The purpose of this notice is to allow for an additional 30 days for public comment until September 20, 2002. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395-7285.

Request written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who

are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection:

(1) *Type of information collection:* Reinstatement, with change, of a previously approved collection for which approval has expired.

(2) *The title of the form/collection:* Budget Detail Worksheet.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form: None. Office of Justice Program, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as brief abstract:* Primary: All potential grantee partners who are possible recipients of our discretionary grant programs. The eligible recipients include state and local government, Indian tribes, profit entities, non-profit entities, educational institutions, and individuals. The form is not mandatory and is recommended as a guide to assist the recipient in preparing the budget narrative as authorized in 28 CFR parts 66 and 70.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 2500 respondents will complete a 4-hour form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total hour burden to complete the forms is 10,000 annual burden hours.

If additional information is required contact: Mrs. Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1600, Patrick Henry Building, 601 D Street, NW., Washington, DC 20530.

Dated: August 15, 2002.

Brenda E. Dyer,

*Department Deputy Clearance Officer,
Department of Justice.*

[FR Doc. 02-21224 Filed 8-20-02; 8:45 am]

BILLING CODE 4410-18-M

DEPARTMENT OF LABOR

Bureau of International Labor Affairs

Request for Information on Forced/ Indentured Child Labor Pursuant to Executive Order 13126; Firecracker Industry in China

AGENCY: Bureau of International Labor Affairs, Labor.

ACTION: Request for information.

SUMMARY: This notice is a request for information to assist the Department of Labor in the examination of whether forced child labor exists in the firecracker industry in China. This review is being conducted pursuant to Executive Order 13126 ("Prohibition of Acquisition of Produced by Forced or Indentured Child Labor") and the "Procedural Guidelines for Maintenance of the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor" in the Federal Acquisition Regulation.

The Department anticipates that written information regarding forced child labor in the firecracker industry in China will aid it in determining, in consultation with the Departments of State and Treasury, whether this product, and its originating country, should be added to the Executive Order list.

DATES: Submitters of information are requested to provide two (2) copies of their written submission to the International Child Labor Program at the address below by September 20, 2002.

ADDRESSES: Written submissions should be addressed to Christine Camillo at the International Child Labor Program, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S-5307, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Christine Camillo, International Child Labor Program, Bureau of International Labor Affairs, at (693-4839; fax (202) 693-4830.

SUPPLEMENTARY INFORMATION:

I. Background

Executive Order No. 13126, which was published in the **Federal Register** on June 16, 1999 (64 FR 32383-32385), declared that it was "the policy of the United States Government * * * that the executive agencies shall take appropriate actions to enforce the laws prohibiting the manufacture or importation of good, wares articles, and merchandise mined, produced or manufactured wholly or in part by forced or indentured child labor". Pursuant to the Executive Order, and

following public notice and comment, the Department of Labor published in the January 18, 2001 **Federal Register**, a final list of products, identified by their country of origin, that the Department, in consultation and cooperation with the Departments of State and Treasury, has a reasonable basis to believe might have been mined, produced or manufactured with forced or indentured child labor. In addition to this list, the Department also published on January 18, 2001, a notice of procedural guidelines for maintaining, reviewing, and, as appropriate, revising the list of products required by Executive Order 13126 [48 CFR subpart 22.15]. The List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor can be accessed on the Internet at www.dol.gov/ilab or can be obtained from: International Child Labor Program (ICLP), Bureau of International Labor Affairs, Room S-5307, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693-4843; fax (202) 693-4830. A copy of the Procedural Guidelines is also available from the International Child Labor Program office.

Pursuant to Section 3 of the Executive Order, the Federal Acquisition Regulatory Councils published a final rule in the **Federal Register** on January 18, 2001, pursuant to that federal contractors who supply products which appear on the list issued by the Department of Labor must certify to the contracting officer that the contractor, or, in the case of an incorporated contractor, a responsible official of the contractor, has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce or manufacture any product furnished under the contract and that, on the basis of those efforts, the contractor is unaware of any such use of child labor. The regulation also imposes other requirements with respect to contracts for products on the Department of Labor's List.

II. China/Firecrackers Executive Order Submission

On June 29, 2001, the Department of Labor accepted for review a submission under Executive Order 13126 regarding the use of forced child labor in the firecracker industry in China. The submission, which was provided by State Department Watch, included information describing a March 2001 incident in which children in Jiangxi Province, China were allegedly killed while being forced to manufacture firecrackers at their school.

III. Definition of Forced/Indentured Child Labor

Under Section 6c of Executive Order 13126—

Forced or indentured child labor means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

IV. Information Sought

The Department is requesting information about the specific child labor incident described above or any other similar incidents where children have been forced to manufacture fireworks in China as well as efforts made by the Government of China to address this problem.

This notice is a general solicitation of comments from the public. All submitted comments will be made a part of the record of the review referred to above and will be available for public inspection.

Signed at Washington, DC, this 15th day of August, 2002.

Thomas B. Moorhead,

Deputy Under Secretary for International Labor Affairs.

[FR Doc. 02–21331 Filed 8–20–02; 8:45 am]

BILLING CODE 4510–28–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–40,609, TA–W–40,609A, TA–W–40,609B, TA–W–40,609C, and TA–W–40,609D]

Leybold Vacuum USA, Inc.; Export, Pennsylvania, Tempe, Arizona, Milwaukee, Oregon, Austin, Texas, San Jose, California; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 12, 2002, applicable to workers of Leybold Vacuum USA, Inc., Export, Pennsylvania. The notice was published in the **Federal Register** on June 24, 2002 (67 FR 42583).

At the request of the petitioners, the Department reviewed the certification

for workers of the subject firm. New information shows that worker separations occurred at the Tempe, Arizona, Milwaukee, Oregon, Austin, Texas and San Jose, California locations of Leybold Vacuum USA, Inc. These employees provided sales and direct field support services supporting the production of dry vacuum pumps and other pumps at the Export, Pennsylvania location of the subject firm.

Based on these findings, the Department is amending this certification to include employees of the Tempe, Arizona, Milwaukee, Oregon, Austin, Texas and San Jose, California facilities of Leybold Vacuum USA, Inc.

The intent of the Department's certification is to include all workers of Leybold Vacuum USA, Inc. who were adversely affected by increased imports.

The amended notice applicable to TA–W–40,609 is hereby issued as follows:

All workers of Leybold Vacuum USA, Inc., Export, Pennsylvania (TA–W–40,609), Tempe, Arizona, (TA–W–40,609A), Milwaukee, Oregon (TA–W–40,609B), Austin, Texas (TA–W–40,609C) and San Jose, California (TA–W–40,609D) who became totally or partially separated from employment on or after December 7, 2000, through June 12, 2004, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC this 15th day of August, 2002.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 02–21333 Filed 8–20–02; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–6022]

Motorola, SDS, BMC, Mesa, Arizona; Notice of Termination of Investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (P.L. 103–182) concerning transitional adjustment assistance, hereinafter called (NAFTA–TAA), and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2273), an investigation was initiated on March 25, 2002, in response to a petition filed on behalf of workers at Motorola, SDS, BMC, Mesa, Arizona.

The petition has been deemed invalid. The three petitioners were separated from the subject firm more than one

year prior to the date of the petition. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC this 13th day of August 2002.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 02–21334 Filed 8–20–02; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request, Submitted for Public Comment and Recommendations; Preparation and Maintenance of Accurate and Up-to-date Certified Mine Maps for Surface and Underground Coal Mines; Submittal of Underground Mine Closure Maps; and, Notification of MSHA Prior to Opening New Mines or the Reopening of Inactive or Abandoned Mines

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the proposed extension of the information collection related to the Record of Mine Closure addressed in 30 CFR 75.1204 and 75.1204–1; the inclusion of standards requiring MSHA notification and inspection prior to mining when opening a new mine or reopening an inactive or abandoned mine addressed in 30 CFR 75.373 and 75.1721; and, the inclusion of standards requiring underground and surface mine operators to prepare and maintain accurate and up-to-date mine maps addressed in 30 CFR 75.1200, 75.1200–1, 75.1201, 75.1202, 75.1202–1, 75.1203, 75.372, 77.1200, 77.1201 and 77.1202.

MSHA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

A copy of the proposed information collection request can be obtained by contacting the employee listed below in the For Further Information Contact section of this notice, or viewed on the Internet by accessing the MSHA home page (<http://www.msha.gov>) and then choosing "Statutory and Regulatory Information" and "Federal Register Documents."

DATES: Submit comments on or before October 21, 2002.

ADDRESSES: Send comments to David . Meyer, Director, Administration and Management, 1100 Wilson Boulevard, Room 2125, Arlington, VA 22209-3939. Commenters are encouraged to send their comments on a computer disk, or via Internet E-mail to *Meyer-David@msha.gov*, along with an original printed copy. Mr. Meyer can be reached at (202) 693-9802 (voice), or (202) 693-9801 (facsimile).

FOR FURTHER INFORMATION CONTACT: Jane E. Tarr, Management Analyst, Records Management Group, U.S. Department of Labor, Mine Safety and Health Administration, Room 2171, 1100 Wilson Boulevard, Arlington, VA 22209-3939. Ms. Tarr can be reached at *Tarr-Jane@msha.gov* (Internet E-mail), (202) 693-9824 (voice), or (202) 693-9801 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Title 30 CFR 75.1200, 75.1200-1, 75.1201, 75.1202, 75.1202-1, and 75.1203 require underground coal mine operators to have in a fireproof repository in an area on the surface of the mine chosen by the mine operator to minimize the danger of destruction

by fire or other hazards, an accurate and up-to-date map of such mine drawn on scale. These standards specify the information which must be shown, the range of acceptable scale, the surveying technique or equivalent accuracy required of the surveying which must be used to prepare the map, that the maps must be certified as accurate by a registered engineer or surveyor, that the maps must be kept continuously up-to-date by temporary notations and must be revised and supplemented to include the temporary notations at intervals not more than 6 months. In addition, the mine operator must provide the MSHA District Manager a copy of the certified mine map annually during the operating life of the mine. These maps are essential to the planning and safe operation of the mine. In addition, these maps provide a graphic presentation of the locations of working sections and the locations of fixed surface and underground mine facilities and equipment, escapeway routes, coal haulage and man and materials haulage entries and other information essential to mine rescue or mine fire fighting activities in the event of mine fire, explosion or inundations of gas or water. The information is essential to the safe operation of adjacent mines and mines approaching the worked out areas of active or abandoned mines. Section 75.372 requires underground mine operators to submit three copies of an up-to-date mine map to the District Manager at intervals not exceeding 12 months.

Title 30 CFR 75.1204 and 75.1204-1 require that whenever an underground coal mine operator permanently closes or abandons a coal mine, or temporarily closes a coal mine for a period of 90 days, the operator shall file with MSHA a copy of the mine map revised and supplemented to the date of closure. Maps are retained in a repository and are made available to mine operators of adjacent properties. The maps are necessary to provide an accurate record of underground areas that have been mined to help prevent active mine operators from mining into abandoned areas that may contain water or harmful gases.

Title 30 CFR 77.1200, 77.1201 and 77.1202 require surface coal mine operators to maintain an accurate and up-to-date map of the mine and specified the information to be shown on the map, the acceptable range of map scales, that the map be certified a registered engineer or surveyor, that the be available for inspection by the Secretary or his authorized representative. These maps are essential for the safe operation of the mine and

provide essential information to operators of adjacent surface and underground mine operators. Properly prepared effectively utilized surface mine maps can prevent outbursts of water impounded in underground mine workings and/or inundations of underground mines by surface impounded water or water and or gases impounded in surface auger mining worked out areas.

Title 30 75.373 and 75.1721 require that after a mine is abandoned or declared inactive and before it is reopened, mine operations shall not begin until MSHA has been notified and has completed an inspection. Standard 75.1721 specifies that the notification be in writing and lists specific information, preliminary arrangements and mine plans which must be submitted to the MSHA District Manager.

II. Current Actions

Mine operators are required to conduct surveying such that mine maps are maintained accurate and up-to-date, the maps must be revised every 6 months and certified accurate by a registered engineer or surveyor and to submit copies of the certified underground maps to MSHA annually and an up-to-date and revised mine closure map whenever an operator permanently closes or abandons a coal mine, or temporarily closes a coal mine for a period of more than 90 days, he or she shall promptly notify the Secretary of such closure.

In addition, mine operators must notify MSHA so that an inspection can be conducted when ever a new mine is opened or a previously abandoned or inactive mine is reopened. The information required to be gathered and recorded on mine maps is essential to the safe operation of the mine and essential to the effectiveness of mandatory inspections and mandated mine plan approval by MSHA. Such information cannot be replaced by any other source and anything less than continuously updated and accurate information would place miner's safety at risk.

The information collected through the submittal of mine closure maps is used by operators of adjacent coal mines when approaching abandoned underground mines. The abandoned mine could be flooded with water or contain explosive amounts of methane or harmful gases. If the operator were to mine into such an area, unaware of the hazards, miners could be killed or seriously injured. In addition, it is in the public interest to maintain permanent records of the locations, extent of workings and potential hazards

associated with abandoned mines. The public safety can be adversely affected by future land usage where such hazards are not known or inaccurately assessed. MSHA collects the closure maps and provides those documents to the Office of Surface Mining, Reclamation & Enforcement for inclusion in a repository of abandoned mine maps. Therefore, MSHA is continuing the certification and application of 30 CFR 75.1204 to assure the required information remains available for the protection of miner's and public safety. In addition, MSHA has added the burden hours and cost estimates for standards which address the preparation and maintenance of certified mine maps for surface and underground coal mines and the notification of MSHA prior to the opening on new coal mines or the

reopening of inactive or abandoned mines.

Type of Review: Reinstatement.
Agency: Mine Safety and Health Administration.

Title: Preparation and Maintenance of Accurate and Up-to-date Certified Mine maps for Surface and Underground Coal Mines; Submittal of Underground Mine Closure Maps; and, Notification of MSHA Prior to Opening New Mines or the Reopening of Inactive or Abandoned Mines.

OMB Number: 1219-0073.

Recordkeeping: Mine operators are required conduct surveying such that mine maps are maintained accurate and up-to-date, the maps must be revised every 6 months and certified accurate by a registered engineer or surveyor and to submit copies of the certified underground maps to MSHA annually and an up-to-date and revised mine closure map whenever an operator

permanently closes or abandons a coal mine, or temporarily closes a coal mine for a period of more than 90 days, he or she shall promptly notify the Secretary of such closure.

In addition, mine operators must notify MSHA so that an inspection can be conducted when ever a new mine is opened or a previously abandoned or inactive mine is reopened. The information required to be gathered and recorded on mine maps is essential to the safe operation of the mine and essential to the effectiveness of mandatory inspections and mandated mine plan approval by MSHA. Such information cannot be replaced by any other source and anything less than continuously updated and accurate information would place miner's safety at risk.

Affected Public: Business or other for-profit.

Cite/reference	Total respondents	Frequency	Total responses	Average time per response (in hours)	Burden hours
75.1200, 75.1200-1, 75.1201, 75.1202, 75.1202-1, 75.1203.	893	Biannual	448	32	14,336
75.1204 & 75.1204-1	724	On occasion	724	2	1,448
75.373 & 75.1721	94	On occasion	94	6	564
77.1200, 77.1201 & 77.1202	1,514	Biannual	757	10	7,580
Total	13,225	1299	23,928

¹ The total respondents are 893 underground mines or 1,514 surface mines; however, 25% of the mine operators perform these tasks utilizing mine-staff, the remaining 75% utilize contracting services. The contracting services are included as an Operating and Maintenance cost (shown below).

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintaining): Contract Surveying and Map preparation \$23,803,160.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: August 16, 2002.

Richard L. Brechbiel,

Deputy Director, Office of Administration and Management.

[FR Doc. 02-21332 Filed 8-20-02; 8:45 am]

BILLING CODE 4510-43-P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting of the Board of Directors

TIME AND DATE: The Board of Directors of the Legal Services Corporation will meet on August 24, 2002. The meeting

will begin at 9 a.m. and continue until conclusion of the Board's agenda.

LOCATION: The Marriott at Metro Center, 775 12th Street, NW., Washington, DC.

STATUS OF MEETING: Open, except that a portion of the meeting may be closed pursuant to a vote of the Board of Directors to hold an executive session. At the closed session, the Corporation's General Counsel will report to the Board on litigation to which the Corporation is or may become a party, and the Board may act on the matters reported. The closing is authorized by the relevant provisions of the Government in the Sunshine Act [5 U.S.C. 552b(c)(10)] and the corresponding provisions of the Legal Services Corporation's implementing regulation [45 CFR 1622.5(h)]. A copy of the General Counsel's Certification that the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

Open Session

1. Approval of agenda.

2. Approval of the minutes of the Board's meeting of June 1, 2002.

3. Approval of the minutes of the Executive Session of the Board's meeting of June 1, 2002.

4. Approval of the minutes of the Board's telephonic meeting of May 23, 2002.

5. Chairman's Report.

6. Members' Report.

7. Acting Inspector General's Report.

8. President's Report.

9. Consider and act on the report of the Board's Committee on Provision for the Delivery of Legal Services.

10. Consider and act on the report of the Board's Operations and Regulations Committee.

11. Consider and act on the report of the Board's Finance Committee.

12. Consider and act on changes to the Board's 2002 meeting schedule.

Closed Session

13. Briefing¹ by the Inspector General on the activities of the Office of Inspector General.

14. Consider and act on the Office of Legal Affairs' report on potential and pending litigation involving LSC.

Open Session

15. Consider and act on other business.

16. Public Comment.

CONTACT PERSON FOR INFORMATION:

Victor M. Fortuno, Vice President for Legal Affairs, General Counsel & Corporate Secretary, at (202) 336-8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S. Cushing, at (202) 336-8800.

Dated: August 16, 2002.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 02-21359 Filed 8-16-02; 5:01 pm]

BILLING CODE 7050-01-P

LEGAL SERVICES CORPORATION**Sunshine Act Meeting of the Board of Directors Finance Committee**

TIME AND DATE: The Finance Committee of the Legal Services Corporation Board of Directors will meet on August 23, 2002. The meeting will begin at 3:30 p.m. and continue until the Committee concludes its agenda.

LOCATION: The Marriott at Metro Center, 775 12th Street, NW, Washington, DC.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of agenda.
2. Approval of the minutes of the Committee's meeting of May 31, 2002.
3. Report on the projected operating expenses for Fiscal Year 2002 based on operating experiences through June 30, 2002.
4. Report on the internal budgetary adjustments.
5. Consider and act on the President's recommendations for Consolidated Operating Budget reallocations.
6. Consider and act on proposed Temporary Operating Budget for Fiscal Year 2003.

¹ Any portion of the closed session consisting solely of staff briefings does not fall within the Sunshine Act's definition of the term "meeting" and, therefore, the requirements of the Sunshine Act do not apply to any such portion of the closed session. 5 U.S.C. 552(b)(2) and (b). See also 45 CFR 1622.2 and 1622.3.

7. Consider and act on budget mark for Fiscal Year 2004, including receipt of public comment.

8. Consider and act on other business.

9. Public comment.

CONTACT PERSON FOR INFORMATION:

Victor M. Fortuno, Vice President for Legal Affairs, General Counsel & Corporate Secretary, at (202) 336-8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S. Cushing, at (202) 336-8800.

Dated: August 16, 2002.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 02-21360 Filed 8-16-02; 5:01 pm]

BILLING CODE 7050-01-P

LEGAL SERVICES CORPORATION**Sunshine Act Meeting of the Board of Directors Operations & Regulations Committee**

TIME AND DATE: The Operations and Regulations Committee of the Legal Services Corporation Board of Directors will meet on August 23, 2002. The meeting will begin at 1 p.m. and continue until the Committee concludes its agenda.

LOCATION: The Marriott at Metro Center, 775 12th Street, NW, Washington, DC.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of agenda.
2. Approval of the minutes of the Committee's meeting of May 31, 2002.
3. A panel of three Executive Directors (Michelle DeBord, MidPenn Legal Services, Inc., Harrisburg, PA; Harold E. Creacy, Ocean-Monmouth Legal Services, Inc., Toms River, NJ; and Paul C. Julien, Southern Arizona Legal Aid, Inc., Tucson, AZ) will discuss their experiences undergoing on-site visits from the Office of Compliance & Enforcement conducting a CSM/CMS review, a technical review, and accountability training.
4. Status report on current open rulemakings and Rulemaking Protocol.
5. Consider and act on Rulemaking Protocol.
6. Consider and act on Limited English Proficiency Guidance.
7. Consider and act on potential identification of new appropriate subject(s) for rulemaking.
8. Consider and act on contract renewals for LSC Vice Presidents Randi

Youells, Mauricio Vivero, and Victor Fortuno.

9. Consider and act on other business.

10. Public comment.

CONTACT PERSON FOR INFORMATION:

Victor M. Fortuno, Vice President for Legal Affairs, General Counsel & Corporate Secretary, at (202) 336-8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S. Cushing, at (202) 336-8800.

Dated: August 16, 2002.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 02-21361 Filed 8-16-02; 5:01 pm]

BILLING CODE 7050-01-P

LEGAL SERVICES CORPORATION**Sunshine Act Meeting of the Board of Directors Committee on Provision for the Delivery of Legal Services**

TIME AND DATE: The Committee on Provision for the Delivery of Legal Services of the Legal Services Corporation Board of Directors will meet on August 23, 2002. The meeting will begin at 9 a.m. and continue until the Committee concludes its agenda.

LOCATION: The Marriott at Metro Center, 775 12th Street, NW, Washington, DC.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of agenda.
2. Approval of the minutes of the Committee's meeting of May 31, 2002.
3. Office of Program Performance (OPP) and Office of Information Management (OIM) "Matters" Project Update by Chris Sundseth and Glenn Rawdon.
4. Update by Randi Youells and John Meyer on 2003 Census Adjustments.
5. Focus on the Field—Presentation by Cynthia Schneider on the Challenges of Delivering Legal Services in Alaska.
6. Update by Althea Hayward on LSC's Diversity Initiatives/Creation of a Grantee Board Training Module on Diversity.
7. Update by Joyce Raby on the 2003 Technology Initiative Grants.
8. State Planning Update by Robert Gross.
9. Update by Reginald Haley on the 2003 Competition.
10. Consider and act on proposed 2003 Grant Assurances.
11. Consider and act on other business.

12. Public comment.

CONTACT PERSON FOR INFORMATION:

Victor M. Fortuno, Vice President for Legal Affairs, General Counsel & Corporate Secretary of the Corporation, at (202) 336-8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S. Cushing, at (202) 336-8800.

Dated: August 16, 2002.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 02-21362 Filed 8-16-02; 5:01 pm]

BILLING CODE 7050-01-P

NUCLEAR REGULATORY COMMISSION

Enforcement Program and Alternative Dispute Resolution; Request for Comments and Announcement of Public Meetings

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for comments and announcement of public meetings.

SUMMARY: On December 14, 2001 (66 FR 64890), the Nuclear Regulatory Commission (NRC) announced its intent to evaluate the use of Alternative Dispute Resolution (ADR) in the NRC's enforcement program, which is defined in the NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)". The NRC is undergoing this evaluation because government-wide, ADR techniques have proven to be efficient and effective in resolving a wide range of disputes. On March 12, 2002, the staff conducted an ADR workshop to evaluate the strengths and weaknesses associated with its use in the enforcement area. The staff has evaluated the outcome of this workshop and concluded that: (1) There may be a role for ADR in the enforcement program; however, further review is needed, (2) if ADR has a role, the NRC should focus on areas resulting in the largest benefits, (3) a pilot program should be the first step to implementation, and (4) additional stakeholder input is needed.

The staff concluded that in order to make any final recommendations for incorporation into the enforcement program or the development of a pilot program, additional stakeholder input is

necessary. As a result, additional comment is being sought and a number of public meetings and workshops are being scheduled at various locations throughout the country. Various options associated with the development of a pilot program for the use of ADR in the enforcement process will be discussed. Information on ADR is available on the NRC's Web site at www.nrc.gov: select What we Do, Enforcement, then Public Involvement in Enforcement.

DATES: The comment period expires October 21, 2002.

ADDRESSES: Submit written responses to the questions contained in the Discussion section of this Notice to Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop T-6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays. Comments may be submitted by e-mail to nrcprep@nrc.gov. Copies of comments received may be examined at the NRC's Public Document Room, located at One White Flint North (O1-F21), Rockville, Maryland, 20852-2738.

FOR FURTHER INFORMATION CONTACT:

Barry Westreich, Senior Enforcement Specialist, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 (301) 415-3456, e-mail bcw@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

"ADR" is a term that refers to a number of voluntary processes, such as mediation and facilitated dialogues, that can be used to assist parties in resolving disputes and potential conflicts. The Administrative Dispute Resolution Act of 1996 (ADRA) encourages the use of ADR by Federal agencies, and defines ADR as "any procedure that is used to resolve issues in controversy, including but not limited to, conciliation, facilitation, mediation, fact finding, mini trials, arbitration, and use of Ombuds, or any combination thereof." 5 U.S.C. 571(3). These techniques involve the use of a neutral third party ("neutral"), either from within the agency or from outside the agency, and are typically voluntary processes in terms of the decision to participate, the type of process used, and the content of the final agreement. Federal agency experience with ADR has demonstrated that the use of these techniques can result in the quicker and more economical resolution of issues, more effective outcomes, and improved

relationships. The NRC has a general ADR Policy, 57 FR 36678; August 14, 1992, that supports and encourages the use of ADR in NRC activities. In addition, the NRC has used ADR effectively in a variety of circumstances, including rulemaking and policy development, and Equal Employment Opportunity (EEO) disputes.

Although a few enforcement cases have been resolved through the use of "settlement judges" from the Atomic Safety and Licensing Board Panel, pursuant to 10 CFR 2.203 there has been no systematic evaluation of the need for ADR in the enforcement process. As a result of previous stakeholder input, the staff is considering the development of a pilot program for the use of ADR in the enforcement process.

Discussion

On December 14, 2001, a **Federal Register** notice (FRN) was issued soliciting comments on the use of ADR in the enforcement process (66FR64890). The 60-day comment period was extended to March 29, 2002. A workshop was held on March 12, 2002. The responses to the FRN and those expressed at the workshop indicated that the views on the appropriateness and potential usefulness of ADR techniques were widely varied. The industry and its legal counsel embraced the use of ADR techniques broadly and the public interest stakeholders were generally opposed to exploring possible uses of ADR in enforcement. Also, many stakeholders appeared to misunderstand what ADR is and how it can be used.

The workshop consisted of an overview of the agency's enforcement program to a panel consisting of: one independent ADR specialist; four ADR specialists from various Federal agencies; representatives from the Nuclear Energy Institute (NEI); representatives from the Union of Concerned Scientists; representatives from two law firms representing nuclear utilities; and, representatives from two law firms representing environmental whistle blowers. The panelists discussed the merits and debated the usefulness of ADR techniques in the context of the enforcement process.

Overall, many of the participants (*i.e.*, industry representatives, agency ADR experts, and an attorney from the environmental whistle blower community) believed that ADR could be used beneficially in the NRC enforcement process. They also did not think that any particular areas of the enforcement process should be eliminated from consideration. These participants noted that any decision to

use ADR was not irrevocable and the results, either from a pilot, or some type of full-scale implementation, would need to be evaluated. The attorney from the environmental whistle blower community who was in favor of ADR confined her suggestions to the use of ADR in 10 CFR 50.7 discrimination cases and suggested a model that the NRC might follow based on DOE experience. Most participants also recommended taking a flexible view on what types of ADR techniques should be used and noted, for example, that facilitation could also be used effectively, as well as mediation. Those participants supporting the use of ADR recommended that a wide pool of third party neutrals should be available for the parties to select from for any particular dispute.

The citizen group representative was opposed to ADR on the grounds that ADR would only provide an opportunity for the enforcement process to be weakened. In written comments, it was noted that if ADR was to have a role, it should only be considered for establishing the fact set that is then used by the NRC staff to determine sanctions, for example, as to when a non-conforming condition was identified or whether the cause of the violation was wilful. However, its use would be "distasteful" when ADR is used in a case that involved a challenge to a proposed sanction. In respect to the potential need for confidentiality in ADR, this commentator noted that more deals brokered behind closed doors can only expand the widely perceived impression that NRC has an inappropriate close relationship with the industry it regulates.

Conclusions and Plans for Developing a Recommendation

Based on review of the comments received and provided during the March 12, 2002, workshop, the staff has reached several conclusions and plans to proceed as follows:

- There *may* be a role for ADR in the enforcement program.

Based on the many pros and cons regarding the use of ADR in the NRC enforcement program and that many of the comments received were opposed on the same issues, the staff cannot draw any final conclusions regarding whether ADR should ultimately have a role in the enforcement program and, if it does have a role, how it should be incorporated. However, based on review of stakeholder input, the staff believes that there are areas in the enforcement program which may benefit from the incorporation of ADR and that these areas should be reviewed further.

The staff needs to specifically evaluate whether the use of ADR will not detract from the overall objective of the NRC enforcement program—deterrence and achieving lasting corrective actions, maintaining safety, increasing (or at least maintaining) public confidence, and increasing (or at least maintaining) effectiveness.

- If ADR has a role, NRC should initially focus efforts on areas resulting in the largest benefits.

Commentors provided a wide range of potential benefits and drawbacks to using ADR. While the staff recognizes that it needs to evaluate all benefits and drawbacks, the staff believes that the largest benefits of implementation of ADR in the enforcement program are greater efficiency, lower costs, and better timeliness. Therefore, the staff plans to narrow the initial focus and scope of its review and evaluation of the use of ADR to areas that would realize these benefits. The staff plans to review whether ADR should be incorporated into one of the following areas of the enforcement program for reactor and materials cases: cases involving potential discrimination and cases involving potential wrongdoing. Historically, these types of cases have taken the most time and resources for all parties involved. However, while the staff plans to limit the scope of its review at this time, the staff is not precluding expanded use of ADR in the future. Specifically, if incorporation of ADR is appropriate and demonstrates a benefit, the staff will review further use of ADR in other areas.

- If ADR has a role, it should initially be implemented as a pilot program.

Based on review of the stakeholder's comments, it is clear that some stakeholders, both internal and external, do not see the benefits of incorporating ADR into the enforcement program. In fact, some believe it will have a negative impact on the enforcement process. Therefore, if the staff recommends incorporation of ADR into the enforcement program, it will recommend initial implementation as a pilot program. The staff believes that implementation of a pilot will better demonstrate whether the benefits can be realized, provide confidence that there will be no, or minimal, negative impacts, and will provide additional information for how ADR can be further incorporated into the enforcement program. For a pilot to be successful in demonstrating the use of ADR, the staff believes that the pilot program should include a representative sample of cases. There should be a sufficient number of cases included in the pilot to adequately exercise the enforcement

process but not too many that will overwhelm the staff and process. The pilot should specifically address at which points in the enforcement process ADR should be used.

The staff notes that use of an ADR pilot program would be voluntary for all parties, including the NRC. Therefore, if implementation of the pilot for a specific case would compromise the enforcement process, NRC could withdraw from ADR for the case. Other parties would have the same option. In such cases, the NRC would follow the current enforcement process.

- Additional stakeholder input is warranted.

As stated, stakeholder input is very mixed on a number of issues important to the use of ADR. In order to make any final recommendations for incorporation of ADR into the enforcement program, or even the development of a pilot program, additional stakeholder interactions are necessary.

In view of the above, the staff seeks additional input from the public and other stakeholders in written form or at workshops to be scheduled throughout the country over the next few months. The staff proposes to evaluate the use of ADR in a pilot program, initially for some percentage of wrongdoing and discrimination cases in both the materials and reactor areas. The staff is currently evaluating whether to use ADR in a number of points in the process. Specifically, (1) following identification of wrongdoing or an allegation of discrimination but prior to a full investigation into the matter, (2) following an investigation that substantiates the matter but prior to an enforcement conference, (3) following the issuance of a Notice of Violation and Proposed Imposition of Civil Penalty but prior to any Imposition of Civil Penalty, and (4) following an Imposition of Civil Penalty but prior to a Hearing on the matter. The staff requests that comments be focused on issues related to the implementation of a pilot program at the above steps in the NRC process, and include factors such as what ADR techniques would be useful at certain points, what pool of neutrals should be used, who should attend the ADR sessions, and what ground rules should be implemented. Also, the staff requests that comments be focused on the pros and cons of ADR as they relate to these points in the process and in maintaining safety, increasing public confidence, and maintaining the effectiveness of the enforcement program for the above noted areas.

The staff also plans to hold several public meetings and workshops at

various locations to solicit stakeholder input. Specifically the staff plans to hold meetings and workshops, tentatively scheduled at the following locations and dates:

- Hanford, WA: Week of September 2, 2002
- Chicago, IL: Week of September 16, 2002
- San Diego, CA: Week of September 23, 2002
- New Orleans, LA: Week of October 7, 2002
- Washington, DC: Week of October 14, 2002

The staff will provide specific information regarding the meeting dates times and locations on the NRC's Web site at www.nrc.gov select What We DO, then Public Involvement in Enforcement. Once the actions identified above have been completed, the staff will provide the Commission a proposed pilot program for approval or will provide an alternative recommendation regarding the use of ADR.

Dated at Rockville, Maryland, this 13th day of August, 2002.

For the Nuclear Regulatory Commission.

Frank J. Congel,

Director, Office of Enforcement.

[FR Doc. 02-21255 Filed 8-20-02; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Subcommittee Meeting on Thermal-Hydraulic Phenomena; Notice of Meeting

The ACRS Subcommittee on Thermal-Hydraulic Phenomena will hold a meeting on September 9, 2002, Room T-2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows: Monday, September 9, 2002—1 p.m. until the conclusion of business.

The Subcommittee will continue its review of the proposed resolution of Generic Safety Issue (GSI)-185, "Control of Recriticality Following Small-Break LOCAs in PWRs." The purpose of this meeting is to gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee

Chairman. Written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the Designated Federal Official named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, and the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the Designated Federal Official, Mr. Paul A. Boehnert (telephone 301-415-8065) between 7:30 a.m. and 5 p.m. (EDT). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes to the agenda that may have occurred.

Dated: August 14, 2002.

Howard J. Larson,

Acting Associate Director for Technical Support, ACRS/ACNW.

[FR Doc. 02-21256 Filed 8-20-02; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Subcommittee Meeting on Fire Protection; Notice of Meeting

The ACRS Subcommittee on Fire Protection will hold a meeting on September 11, 2002, Room T-2B3, 11545 Rockville Pike, Rockville, Maryland.

The agenda for the subject meeting shall be as follows: Wednesday, September 11, 2002—8:30 a.m. until the conclusion of business.

The Subcommittee will review the staff's Fire Protection Research Plan, status of fire protection research activities, fire protection inspection

process and findings, and other related matters, including industry activities. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify one of the ACRS staff engineers named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, and the Chairman's ruling on requests for the opportunity to present oral statements and allotted therefor can be obtained by contacting either Mr. Sam Duraiswamy (telephone 301/415-7364) or Mr. Timothy J. Kobetz (Telephone 301-415-8716) between 7:30 a.m. and 4:15 p.m. (EDT). Persons planning to attend this meeting are urged to contact one of the above named individuals at least two working days prior to the meeting to be advised of any potential changes to the agenda that may have occurred.

Dated: August 14, 2002.

Howard J. Larson,

Acting Associate Director for Technical Support, ACRS/ACNW.

[FR Doc. 02-21257 Filed 8-20-02; 8:45 am]

BILLING CODE 7590-01-P

PEACE CORPS

Proposed Peace Corps Information Quality Guidelines

AGENCY: Peace Corps.

ACTION: Proposed guidelines.

SUMMARY: These proposed information quality guidelines are required by law and are intended to ensure and maximize the quality of information disseminated to the public by the Peace Corps. The guidelines are based on those issued by the Office of Management and Budget (OMB) on January 3, 2002 (67 FR 369–378), as corrected and reprinted on February 22, 2002 (67 FR 8451–8460). The guidelines set out the Agency's policies and procedures for ensuring the quality (objectivity, utility, and integrity) of information provided to the public. The guidelines also establish administrative mechanisms permitting affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the Agency that does not comply with the OMB or its own guidelines. These guidelines represent Agency policy and procedures and have no legal effect and do not create any legal rights or obligations.

DATES: Public comment is requested on the guidelines. Comments must be received September 20, 2002.

ADDRESSES: Comments should be submitted to Suzanne B. Glasow, Associate General Counsel, Office of the General Counsel, 1111 20th Street NW., Washington, DC 20526.

FOR FURTHER INFORMATION CONTACT: Suzanne B. Glasow, Associate General Counsel, 202–692–2150.

SUPPLEMENTARY INFORMATION: OMB issued guidelines on January 3, 2002 (67 FR 369–378), as corrected and reprinted on February 22, 2002 (67 FR 8451–8460), to implement Section 515 of the Treasury and General Government Appropriations Act for FY 2001) Public Law 106–554, HR 5658). Section 515 and the OMB Guidelines require each federal agency subject to the Paperwork Reduction Act to issue its own guidelines that provide policies and procedures used by the Agency to ensure the objectivity, utility, and integrity of information disseminated by the Agency. The guidelines must also establish administrative mechanisms allowing affected persons to obtain correction of information disseminated to the public that does not comply with the OMB and Agency guidelines. The Peace Corps requests public comment on these proposed guidelines.

Guidelines for Ensuring and Maximizing the Quality of Information Prior to Public Dissemination

Section I Purpose

These guidelines are intended to set out the Agency's procedures for

ensuring the quality of information it disseminates to the public.

Section II Definitions

1. "Affected persons" are those who may directly benefit or be harmed by the disseminated information, including: (a) Persons seeking to address information about themselves or about the persons to whom they are directly related or publicly associated; and (b) persons that may reasonably be expected to experience significant adverse impact to their financial interests as a result of the information deficiency.

2. "Dissemination" means the distribution of information initiated or sponsored by the Peace Corps to the general public within the United States. Dissemination does not include distribution of information or other materials that are:

(a) Intended for government employees, including Peace Corps employees and Volunteers, or government contractors or grantees (for example: directories, staffing information, internal manuals; cables);

(b) Intended for U.S. Government agencies;

(c) Produced in response to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or similar laws;

(d) Correspondence or other communications limited to individuals (examples include questions or concerns about individual passports, visas, adoptions, missing persons, applications for employment, or federal benefits) or to other persons, as defined in this section;

(e) Distributed to the press as a summary of a recent event or Peace Corps action;

(f) Archival records; public filings; responses to subpoenas or compulsory document productions; or

(g) Documents prepared and released in the context of adjudicative processes. (These guidelines do not impose any additional requirements on agencies during adjudicative proceedings and do not provide parties to such adjudicative proceedings any additional rights of challenge or appeal.)

3. "Influential," when used in the phrase "influential scientific, financial, or statistical information," refers to a narrow category of information with respect to which an agency can reasonably determine that dissemination will have a clear and substantial impact on important public policies or important private sector decisions. To be considered influential, information must be based on objective and quantifiable data that constitute a

principal basis for substantive policy positions adopted by the Peace Corps. Any influential information to be disseminated by the Peace Corps is reviewed for quality by the Agency, or another agency within the federal government, depending on who is primarily responsible for developing such information. Where circumstances deem it appropriate, the Agency may include the identity of the federal government agency or international organization originating any cited influential information in information disseminated by the Peace Corps.

4. "Information," for purposes of these guidelines, means any communication or representation of knowledge, such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that Peace Corps disseminates on the Agency's external web page, but does not include the provision of hyperlinks to information that others disseminate. "Information" does not include:

(a) Statements on foreign policy or that might cause harm to the national security;

(b) Information originated by, and attributed to, non-Peace Corps sources, provided the Peace Corps does not expressly rely on it;

(c) Opinions, where the Agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the Agency's views;

(d) Statements related solely to the internal personnel rules and practices of the Peace Corps or materials produced for Peace Corps employees, contractors, Volunteers, agents or alumni;

(e) Descriptions of the Peace Corps, its responsibilities and its organizational components;

(f) Testimony of Peace Corps officials before courts, administrative bodies, or Congress;

(g) Investigatory material compiled pursuant to U.S. law or for law enforcement purposes in the United States or abroad; or

(h) Statements which are, or which reasonably may be expected to become, the subject of litigation, whether before a U.S. or foreign court or in an international arbitral or other dispute resolution proceeding.

5. "Integrity" refers to the security of information, that is, the protection of the information from unauthorized access, revision, corruption, or falsification.

6. "Objectivity" addresses whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner,

including background information where warranted by the circumstances.

7. "Person" means an individual, an organization, or a State or local government or division thereof.

8. "Quality" is an umbrella term comprising the terms "utility," "objectivity," and "integrity."

9. "Utility" refers to the usefulness of the information to its intended users.

Section III Procedures To Ensure the Quality of Information

The Peace Corps is committed to providing the public with reliable and useful information. To meet this goal, the Agency collects information from as many reasonably available and reliable sources as appropriate and subjects draft information intended for public dissemination to a thorough review process. Quality control procedures apply at all stages of the information lifecycle, including the times of creation, collection, maintenance, and dissemination.

A. Objectivity and Utility of Information

1. The office collecting and drafting information intended for public dissemination has the primary responsibility to follow quality control procedures, pursuing the most knowledgeable and reliable sources reasonably available through the Agency's resources and by confirming the objectivity and utility of information internally within the office, with all interested Agency offices, and with other government agencies, when appropriate.

2. The Agency's quality control system for information dissemination is based generally on the "action" and "clearance" processes. The action process constitutes the work done by the office responsible for the product. The "clearance" process involves the review of the product by offices who are authorized to provide clearance and approval of the product. This dual process places responsibility for action upon a particular office while ensuring that the information and opinions of other offices are brought to bear on the proposed action.

3. The action office should assign an action to an "action officer," typically the principal drafter. The action officer will follow any office specific quality review procedures and consult informally with officers in other interested offices before preparing the information. The action officer's role includes:

(a) Preparing an action document after consulting the necessary materials and people, including government and non-government sources, as appropriate;

(b) Determining clearance points;

(c) Making the initial determination as to where the final decision shall be made;

(d) Obtaining clearances and approvals; and

(e) Overcoming delays and, if necessary, presenting the matter to higher authority.

4. Clearances or approvals of information for dissemination are generally obtained from any office within the Peace Corps or any other agency within the federal government that has a substantive interest in the information. If an office designated for clearance disagrees with the information and differences cannot be resolved at that level, the matter is raised to an Agency official at a higher level.

5. Action officers may also seek advice from other offices having a collateral interest in the subject matter of the information. Offices with collateral interests are offices whose field of responsibility is not vitally affected by the proposed action, but they may have useful information or views to contribute. Clearances from such offices are not required.

6. Where there are differences in views within the Agency concerning proposed information, the differences are generally documented and explained to offices asked to clear or approve the document. After reasonable efforts have been made to resolve any substantive differences, superior officers are informed of the dissenting views and made the necessary decisions. Final clearance of all publications developed for public dissemination must be cleared by the Senior Publications Manager.

7. While the "action" and "clearance" processes are general requirements for a range of information dissemination actions, there are specific requirements for certain categories of information dissemination. For example, information disseminated on the Agency's external web site must be cleared by the Agency's Internet Communications Director. Information disseminated on the Agency's internal web site must be cleared by the Agency's Intranet Manager.

8. The quality of the Agency's disseminated information is also controlled by limits on who may speak on behalf of the Agency. The Agency's Director of Communications has been delegated authority to speak on behalf of the Peace Corps.

9. When the Agency disseminates reports or other statements, it seeks input from multiple qualified and expert sources. The Agency also attempts to corroborate all information

received. In instances where statements cannot be corroborated adequately, those statements are accompanied by attribution to the source, wherever practicable, to assist the reader in assessing their credibility. Where the Agency disseminates conclusions on an issue, effort is made to identify the facts or events upon which the conclusions are based, to the extent appropriate.

B. Integrity of Information

1. "Integrity" refers to the security of information (paper, electronic and other forms), including the protection of the information from unauthorized access, revision, or from being compromised through corruption or falsification.

2. The security of electronic information is the responsibility of the Chief Information Officer (CIO) who approves new policies, oversees security operations related to Agency-wide information resources, management, and systems, and engages in policy development and planning.

3. Within the Agency, the Information Technology (IT) security program gives every Agency staff member general responsibility for the security of the IT systems they use. Technology implementers and the Agency's senior staff are assigned more explicit responsibilities. The IT Security Program Manager's role includes developing and maintaining an information security program, promoting effective implementation and maintenance of information security policies and procedures, controlling techniques throughout the Agency, and training, overseeing and assisting Agency personnel with significant information security related responsibilities. Under the CIO, the Agency develops, implements, and maintains new computer software and hardware systems and provides operational support for systems and system users.

4. Assisted by the IT Security Program Manager, office directors and program managers are primarily responsible and accountable for the integrity of information within their offices. On a day-to-day basis, the responsibilities are carried out by the managers of networks, systems and applications. These technical personnel assess and manage the information security risks associated with the operations and assets for programs and systems within their control. In that capacity, the technical personnel determine the levels of information security appropriate to protect such operations and assets and periodically test and evaluate information security controls and techniques.

5. The security of paper and other forms of information, other than electronic information, is the responsibility of the Director of Security.

Section IV Requests for Correction of Information

The Peace Corps works to be responsive to users of its information and to improve its information products. The procedures set out in this section are available to "affected" persons who seek to correct information publicly disseminated by the Peace Corps and apply to information disseminated by the Peace Corps on or after October 1, 2002.

1. Persons seeking to correct information publicly disseminated by the Peace Corps must send a written request to the Senior Publications Manager, Office of the Director, 1111 20th Street, NW., Washington, DC 20526.

2. Requests for correction are presumed timely if submitted within sixty (60) days of the dissemination date of the information being challenged.

3. Requests will be assigned a reference number and a notice of receipt of the request will be sent to the requester.

4. The reviewing office will give the request due consideration, including a review of the disseminated information at issue and other materials, as appropriate.

5. In determining whether a response to the request for correction is appropriate, the reviewing office shall consider the following factors:

(a) Whether the statements challenged by the requester fall within the scope of "information" that has been disseminated by the Agency, as those terms are defined in these guidelines;

(b) Whether the requester is "affected" by the information at issue, as that term is defined in these guidelines;

(c) The importance of the formations involved; and

(d) The nature and extent of the request and the public benefit of making the requested correction.

6. A request will not be considered if the Agency determines:

(a) It is not submitted by an "affected" person, as that term is defined in these guidelines;

(b) It does not involve the correction of information publicly disseminated by the Peace Corps;

(c) It is not timely; or

(d) Consideration of the request would not advance material interests of the requester, the general public, or the Peace Corps.

7. Where the reviewing office determines that the information publicly disseminated by the Agency was incorrect, it may take corrective measures, as appropriate, recognizing the potential implications for the requester, the United States, and the Agency, without disrupting Agency process.

8. Where the Agency determines that a response under these guidelines is not appropriate, it will so advise the requester.

9. In most cases, where response under these guidelines is appropriate, the Agency will respond within sixty (60) days of request. The requester will be notified if additional time is required. Agency responses will describe the disposition of the request, the reasons for the disposition, and any corrective action taken or pending.

10. Subject to applicable law, rules or regulations, notice of corrective measures may include, but are not limited to, personal contacts via letter, press releases, or posting on the Agency's website. Notice of corrective measures, where appropriate, should be designed to provide reasonable notice to all affected persons.

Section V Procedures for Requesting Reconsideration

1. An affected person who received notice from the Agency of the disposition of his or her request under Section IV of these guidelines, may request consideration of the disposition, unless the disposition was a determination that a response to the request was not appropriate.

2. To request reconsideration, the requester shall make the request in writing to the Director of the Peace Corps, and include a copy of original request for correction previously submitted to the Agency. The request for reconsideration shall be sent to the Office of the Director, 1111 20th Street, NW., Washington, DC 20526. Requests for Reconsideration must be submitted within thirty (30) days of the date of the Agency's disposition notification to the requester.

3. Requests for Reconsideration shall be reviewed by the Director or designee. The Director or designee shall apply the same standards and procedures applicable to the original request for correction.

4. The Agency will generally respond within sixty (60) days of receipt of the request. The requester will be informed of the disposition of the request and reasonable notice shall be given affected persons of any corrective actions taken. The decision shall constitute a final action by the Agency.

Dated: August 15, 2002.

Tyler S. Posey,

General Counsel.

[FR Doc. 02-21304 Filed 8-20-02; 8:45 am]

BILLING CODE 6015-01-M

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application to Withdraw from Listing and Registration on the American Stock Exchange LLC (Carolina Power & Light Company, \$5.00 Preferred Stock, no par value) File No. 1-13382

August 15, 2002.

Carolina Power & Light Company, a North Carolina corporation ("Issuer"), has filed an application with the Securities and Exchange Commission ("Commission"), pursuant to section 12(d) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 12d2-2(d) thereunder,² to withdraw its \$5.00 Preferred Stock, no par value ("Security"), from listing and registration on the American Stock Exchange LLC ("Amex" or "Exchange").

The Issuer stated in its application that it has met the requirements of Amex Rule 18 by complying with all applicable laws in effect in the state of North Carolina, in which it is incorporated, and with the Amex's rules governing an issuer's voluntary withdrawal of a security from listing and registration. The Issuer's application relates solely to the Security's withdrawal from listing on the Amex and from registration under section 12(b) of the Act,³ and shall not affect its obligation to be registered under section 12(g) of the Act.⁴ The Board of Directors ("Board") of the Issuer unanimously approved a resolution on March 20, 2002 to withdraw the Issuer's Security from listing on the Amex. In making the decision to withdraw its Security from the Amex, the Board states that although the Security was originally listed on the Amex to provide a liquid market and better exposure for the Security, current trading volumes are very small, and with the significant technological improvements by the stock exchanges and the availability of online order processing and broader coverage by the broker community nationwide, the advantages of listing no longer exist.

¹ 15 U.S.C. 78j(d).

² 17 CFR 240.12d2-2(d).

³ 15 U.S.C. 78j(b).

⁴ 15 U.S.C. 78j(g).

The Issuer will seek quotation of its Security on the OTC Bulletin Board.

Any interested person may, on or before September 9, 2002, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁵

Jonathan G. Katz,
Secretary.

[FR Doc. 02-21318 Filed 8-20-02; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-46362; File No. SR-Amex-2002-38]

Self Regulatory Organizations; American Stock Exchange LLC; Order Granting Approval to Proposed Rule Change and Amendment No. 1 Thereto To Designate the New Trading Floor on the Ground Floor of the Exchange as a "Separate Trading Area"

August 15, 2002.

On April 23, 2002, the American Stock Exchange LLC ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to designate the new trading floor on the ground floor of the Exchange ("Harry's") as a "separate trading area."

On June 6, 2002, the Amex submitted Amendment No. 1 to the proposed rule change.³ The proposed rule change was published for comment in the **Federal Register** on July 5, 2002.⁴ The

Commission received no comment letters on the proposal.

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange⁵ and, in particular, the requirements of section 6 of the Act⁶ and the rules and regulations thereunder. The Commission finds specifically that the proposed rule change is consistent with section 6(b)(5) of the Act⁷ because it is designed to prevent fraudulent and manipulative acts and practices, and promote just and equitable principles of trade.

The Commission previously approved similar proposals by the Amex to designate the sections of its trading floor as separate trading areas for the purposes of stock and options trading.⁸ In these Orders, the Commission required that the trading of stocks and their related options be sufficiently separated in a manner that minimized the time and place advantages that could be derived from the proximity of the equity and options trading areas. In addition to the physical separation of the trading locations of equities and their related options, Amex Rule 958(f) prohibits jointly registered equity and options traders from entering options transactions on a Paired Security⁹ for one hour after leaving the equity floor where the underlying security trades. Finally, the Orders restricted the use of hand signals or other like means of communication between members to communicate between floors.

The Commission is satisfied that these conditions are met here. Options on both listed and non-Amex-listed equities are traded on Harry's while Amex-listed equities are traded on the Main Trading Floor. Harry's is located in a separate area on the ground floor of the Exchange and is only accessible from the Exchange's other trading locations by escalator. Accordingly, the trading posts located on Harry's are not visible from the Main Trading Floor. Furthermore, the Exchange represents

⁵ In approving this proposed rule change, the Commission notes that it has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

⁶ 15 U.S.C. 78f.

⁷ 15 U.S.C. 78f(b)(5).

⁸ Securities Exchange Act Release Nos. 26147 (October 3, 1988), 53 FR 39556 (October 7, 1988) ("1988 Order"); 34359 (July 12, 1994), 59 FR 36799 (July 19, 1994) ("Index Order"); and 39631 (February 9, 1998), 63 FR 8229 (February 18, 1998) ("1998 Order") (collectively "Orders").

⁹ Generally, a Paired Security is a security which is the subject of securities trading on the Exchange and options trading on the Exchange. See Amex Rule 900(b)(38).

that it maintains adequate surveillance systems designed to prevent trading abuses and manipulation as well as to ensure compliance with the relevant Exchange rules consistent with the 1988, 1998 and Index Orders.¹⁰ Further, the Commission notes that the Exchange's rules regarding Paired Securities would prohibit the trading of an equity in the same physical location as its related option.¹¹

Therefore, the Commission finds that Harry's is a separate trading area for purposes of trading options on Amex-listed and non-listed stocks. The Commission's approval is premised on the belief that the Amex's proposed trading locations for equities and options are sufficiently separated such that there is no time and place advantage derived from the physical proximity of Harry's to locations where the underlying equities trade. Accordingly, any decision by the Amex to change the location of the designated options relative area to the designated stock area or to modify the means of access between them, would require the submission of a proposed rule change under section 19(b) of the Act.¹²

It is therefore ordered, pursuant to section 19(b)(2) of the Act,¹³ that the proposed rule change and Amendment No. 1 thereto (File No. SR-Amex-2002-38) are approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.¹⁴

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 02-21322 Filed 8-20-02; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-46363; File No. SR-CBOE-2002-23]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to Extension of the Permissible Maturity of FLEX Index Options to Ten Years

August 15, 2002.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934

¹⁰ Telephone Conversation between Jeffrey P. Burns, Assistant General Counsel, Amex, and Christopher Solgan, Law Clerk, Division, Commission, on August 13, 2002.

¹¹ See Amex Rules 900(b)(38), (40), and (41).

¹² 15 U.S.C. 78s.

¹³ 15 U.S.C. 78s(b)(2).

¹⁴ 17 CFR 200.30-3(a)(12).

⁵ 17 CFR 200.30-3(a)(1).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See letter from Jeffrey P. Burns, Assistant General Counsel, Amex, to Nancy Sanow, Assistant Director, Division of Market Regulation ("Division"), Commission, dated June 5, 2002 ("Amendment No. 1").

⁴ See Securities Exchange Act Release No. 46131 (June 27, 2002), 67 FR 44900.

("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on April 30, 2002, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend CBOE Rule 24.4A, "Terms of FLEX Options," to provide a maximum term of ten years for Flexible Exchange ("FLEX") index options under certain circumstances.

The text of the proposed rule change is available at the CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of, and basis for, the proposed rule change, and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Currently, under CBOE Rule 24A.4(a)(4)(i), FLEX index options are limited to a maturity of five years. The purpose of the proposal is to allow FLEX index options traded on the CBOE to have a maturity beyond five years and up to ten years in certain circumstances.

FLEX index option have traded on the CBOE since February 1993.³ FLEX index options provide investors with the ability to customize basic option features including size, expiration date, exercise style, and certain exercise prices. Currently, FLEX index options are limited to a maximum term of five years. The CBOE states that the Exchange recently has received numerous requests from broker-dealers

to extend the maturity of FLEX index options to ten years. According to the CBOE, among the reasons broker-dealers have been interested in seeking an extension in the allowable maturity is that some of their institutional customers trade or issue securities with five- to ten-year terms and are seeking a method to hedge that long-term risk.

The proposed amendment to CBOE Rule 24A.4(a)(4)(i) would permit FLEX index options with terms up to a maximum of ten years when requested by a Submitting Member if the FLEX Post Official determines that sufficient liquidity exists among FLEX index participating members. According to the CBOE, the liquidity requirement will help to ensure that there is not a proliferation of longer-term FLEX index options series where no interest in trading such options exists.⁴

The CBOE states that the proposal will allow institutions to use longer-term FLEX index options to protect portfolios from long-term market moves with a known and limited cost. The CBOE believes that the proposal will better serve the long-term hedging needs of institutional investors and provide those investors with an alternative to hedging their portfolios with off-exchange customized options and warrants.

The CBOE states that by allowing for the extension of the maturity of FLEX index options to ten years in situations where there is demand for a longer-term expiration and where there is sufficient liquidity among FLEX index participating members to support the request, the proposal will better serve the needs of the CBOE's customers and the CBOE members who make a market for such customers. The CBOE believes that the proposal is consistent with and furthers the objectives of section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

⁴ The CBOE notes that the Commission approved a CBOE rule change that permits the listing of FLEX equity options with terms from three to five years under similar circumstances. See Securities Exchange Act Release No. 39524 (January 8, 1998), 63 FR 3009 (January 20, 1998) (order approving File No. SR-CBOE-97-57).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CBOE. All submissions should refer to file number SR-CBOE-2002-23 and should be submitted by September 11, 2002.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁵

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02-21323 Filed 8-20-02; 8:45 am]

BILLING CODE 8010-01-P

⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 31920 (February 24, 1993), 58 FR 12280 (March 3, 1993) (order approving File No. SR-CBOE-92-17).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-46357; File No. SR-NASD-2002-111]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the National Association of Securities Dealers, Inc. to Amend Nasdaq's Transaction Credit Pilot Program for Exchange-Listed Securities to Eliminate Volume Eligibility Thresholds

August 15, 2002.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on August 9, 2002, the National Association of Securities Dealers, Inc. ("NASD" or "Association"), through its subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to amend NASD Rule 7010(c)(2) to modify Nasdaq's transaction credit pilot program for exchange-listed securities. Nasdaq will implement the proposed rule change on a retroactive basis, as of July 1, 2002. The text of the proposed rule change is below. Proposed new language is in italics; proposed deletions are in brackets.

7010. System Services

(a)-(b) No change.

(c)(1) No change.

(2) Exchange-Listed Securities Transaction Credit[.]

For a pilot period, [qualified] NASD members that trade securities listed on the NYSE and Amex in over-the-counter transactions reported by the NASD to the Consolidated Tape Association may receive from the NASD transaction credits based on the number of trades so reported. [To qualify for the credit with respect to Tape A reports, an NASD member must account for 500 or more average daily Tape A reports of over-the-counter transactions as reported to the Consolidated Tape during the concurrent calendar quarter. To qualify

for the credit with respect to Tape B reports, an NASD member must account for 500 or more average daily Tape B reports of over-the-counter transactions as reported to the Consolidated Tape during the concurrent calendar quarter. If an NASD member is so qualified to earn credits based either on its Tape A activity, or its Tape B activity, or both, that] An NASD member may earn credits from one or both pools maintained by the NASD, each pool representing 40% of the revenue paid by the Consolidated Tape Association to the NASD for each of Tape A and Tape B transactions. [A qualified] An NASD member may earn credits from the pools according to the member's pro rata share of the NASD's over-the-counter trade reports in each of Tape A and Tape B for each calendar quarter, [starting with July 1, 2000 for Tape A reports (April 1, 2000 for Tape B reports) and] ending with the calendar quarter starting on October 1, 2002.

(d)-(r) No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq's InterMarket is a quotation, communication, and execution system that allows NASD members to trade stocks listed on the New York Stock Exchange ("NYSE") and the American Stock Exchange ("Amex").³ The InterMarket competes with regional exchanges like the Chicago Stock Exchange ("CHX") and the Cincinnati Stock Exchange ("CSE") for retail order flow in stocks listed on the NYSE and the Amex. InterMarket comprises the Computer Assisted Execution System ("CAES"), a system that facilitates the execution of trades in listed securities

between NASD members that participate in InterMarket, and the Intermarket Trading System ("ITS"), a national market plan system that permits trades between NASD members and specialists on the floors of national securities exchanges that trade listed securities.⁴

Nasdaq is proposing to modify the InterMarket Transaction Credit Pilot Program (the "Program") that it began in 1999.⁵ Under the Program, Nasdaq shares a portion of the tape revenues that it receives (through the NASD) from the Consolidated Tape Association (the "CTA"), by providing a transaction credit to members who engage in OTC trading activity in NYSE and Amex securities. The Program helps InterMarket market makers and investors lower costs associated with trading listed securities. The Program is also a tool for Nasdaq to compete against other exchanges (particularly CSE and CHX) that offer similar programs.⁶

Under the Program, Nasdaq calculates two separate pools of revenue from which credits can be earned: one representing 40% of the gross revenues received from the CTA for providing trade reports in NYSE-listed securities executed in the InterMarket for dissemination by the CTA ("Tape A"), the other representing 40% of the gross revenue received from the CTA for reporting Amex trades ("Tape B"). Eligibility for transaction credits is based on concurrent quarterly trading activity.

Nasdaq is proposing to eliminate the requirement that a member print an average of 500 daily trades of Tape A securities during a quarter to qualify for Tape A sharing, as well as the comparable volume threshold for Tape B securities. Nasdaq originally included these thresholds in the Program because it believed that a member should

⁴ See CAES/ITS User Guide, www.intermarket.nasdaqtrader.com at p.5.

⁵ See Securities Exchange Act Release No. 41174 (Mar. 16, 1999), 64 FR 14034 (Mar. 23, 1999) (SR-NASD-99-13). The SEC issued notice of subsequent extensions of the Program. See Securities Exchange Act Release Nos. 42095 (Nov. 3, 1999), 64 FR 61680 (Nov. 12, 1999) (SR-NASD-99-59); 42672 (Apr. 12, 2000), 65 FR 21225 (Apr. 20, 2000) (SR-NASD-2000-10); 42907 (June 7, 2000), 65 FR 37445 (June 14, 2000) (SR-NASD-2000-32); 43831 (Jan. 10, 2001), 66 FR 4882 (Jan. 18, 2001) (SR-NASD-2000-72); 44098 (Mar. 23, 2000), 66 FR 17462 (Mar. 30, 2001) (SR-NASD-01-15); 44734 (Aug. 22, 2001), 66 FR 4537 (Aug. 26, 2001) (SR-NASD-2001-42); 45273 (Jan. 14, 2002), 67 FR 2716 (Jan. 18, 2002) (SR-NASD-2001-92); and 46232 (July 19, 2002), 67 FR 48691 (July 25, 2002) (SR-NASD-2002-94).

⁶ See Securities Exchange Act Release No. 38237 (Feb. 4, 1997), 62 FR 6592 (Feb. 12, 1997) (SR-CHX-97-01) and Securities Exchange Act Release No. 39395 (Dec. 3, 1997), 62 FR 65113 (Dec. 10, 1997) (SR-CSE-97-12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Nasdaq's InterMarket formerly was referred to as Nasdaq's Third Market. See Securities Exchange Act Release No. 42907 (June 7, 2000); 65 FR 37445 (June 14, 2000) (SR-NASD-2000-32).

demonstrate a clear commitment to operating in the InterMarket by achieving the threshold levels of trading before being eligible for tape sharing. Nasdaq has now concluded that the thresholds should be eliminated, however, for a number of reasons. First, the advent of riskless principal trade reporting,⁷ which often eliminates the need to report one part of a two-part transaction, has reduced the number of trades reported for a given level of transaction activity and thereby made the 500-trade threshold more difficult for certain participants to meet. Second, the tape sharing programs of Nasdaq's competitors, such as CSE and CHX, do not have similar threshold requirements. For these reasons, Nasdaq believes that the thresholds should be eliminated, so that the tape sharing program will be available to all members that participate in InterMarket, regardless of their level of activity.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the Act, including section 15A(b)(5) of the Act,⁸ which requires that the rules of the NASD provide for the equitable allocation of reasonable fees, dues, and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls. The elimination of the volume threshold requirement for transaction credits will increase the number of market participants eligible for transaction credits, thereby lowering the cost of InterMarket transactions.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NASD consents, the Commission will:

A. by order approve such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR-NASD-2002-111 and should be submitted by September 11, 2002.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁹

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02-21319 Filed 8-20-02; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-46361; File No. SR-NASD-2002-102]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by National Association of Securities Dealers, Inc. To Amend the Fee Schedule for the Nasdaq Application of the Primex Auction System®

August 15, 2002.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 31, 2002, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which items have been prepared by Nasdaq. Nasdaq has designated this proposal as one constituting a fee filing under section 19(b)(3)(A) of the Act,³ which renders the rule effective upon the Commission's receipt of this filing. Nasdaq will begin assessing fees pursuant to the revised fee schedule beginning on August 1, 2002. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

Nasdaq proposes to amend NASD Rule 7010(r) to modify the fee schedule for the Nasdaq Application of the Primex Auction System ("Primex"). Nasdaq will implement the proposed rule change on August 1, 2002. The text of the proposed rule change is below. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

(r) Nasdaq Application of the Primex Auction System

The following charges shall apply to the use of the Nasdaq Application of the Primex Auction System:

(1) Transaction charges

Execution services—for all participants:

- Order entry No fee

⁷ Securities Exchange Act Release No. 41606 (July 8, 1999); 64 FR 38226 (July 15, 1999) (SR-NASD-98-08) (approving riskless principal trade reporting for InterMarket); Securities Exchange Act Release No. 43469 (Oct. 20, 2000), 65 FR 64468 (Oct. 27, 2000) (SR-NASD-2000-60) (delaying implementation of riskless principal reporting rules until February 1, 2001).

⁸ 15 U.S.C. 78o-3(b)(5).

⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

• Auction Response (per share, per execution [—\$5.00 maximum]).*	\$ [.01].005
Matching Rights—Primex Auction Market Makers (PAMMs) only:	
• 50 Percent Match	No fee
• Two-Cent Match (per share, per retained order—\$2.50 Maximum).**.***	\$.0025
Revenue Sharing—PAMMs only:	
• Each order executed: ***	1/3 of transaction fee
(2) Monthly Access fees	
<i>Software</i>	
• Workstation license or unique logon:	Per workstation logon:
Stations/logons 1–10	\$200
Stations/logons 11–25	\$100
Stations/logons 26 and above.	\$50
• Proprietary interface license:	Per license:
API specification	\$500
FIX (customized protocol).	\$500
<i>Network</i>	
• Dedicated line:	Per line:
256K	\$1,781
64K with non-guaranteed 256K burst capacity [primary with backup].	\$1,564
56K	\$712
Installation/Uninstall \$1,000 per Nasdaq Staff site visit	

*This fee applies to both Indications and “real-time” Responses. When two orders match directly, a fee is charged to the party that entered the second order.

**This fee is charged in the event a PAMM attaches its matching right to an order, and the crowd offers two cents or less price improvement to that order.

***Paid to a PAMM when it enters an order that interacts with crowd interest in the system. Revenue sharing applies only to orders in those securities in which the firm is registered as a PAMM. The revenue sharing amounts will be paid on a quarterly basis.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The amendments modify NASD Rule 7010(r), which establishes the fee schedule for Primex. Specifically, the amendments reduce the auction response fee from \$.01 to \$.005 per execution, per share, and remove the \$.005 maximum fee cap per execution. In addition, the amendments establish the fees for two additional bandwidth options Nasdaq will begin providing to members that access Primex.

While the fee schedule for Primex was filed initially in December 2001, the prices for the fee schedule were established in 2000.⁴ Nasdaq represents that since that time transaction prices in the overall market have decreased and, as a result, the Primex fee schedule is no longer competitive. This proposal responds to the developments in the market and reduces the auction response fee. With the reduction in the auction response fee, Nasdaq also is eliminating the provision capping the per execution fee at \$.005. Nasdaq represents that the cap was intended to make Primex pricing competitive for the execution of large orders. However, with the new, lower per share charge, Nasdaq believes the pricing is competitive even without the cap.

This proposal also establishes the fees for two new bandwidth options for accessing Primex. Nasdaq currently provides a 64 kilobyte per second (“K”) connection that automatically increases to 256K if needed due to increased message traffic (“burst capacity”). The increase to 256K, however, is constrained, and may not be available, if other users are already using the burst capacity. The charge for this bandwidth option will remain unchanged. The two new bandwidth options will accommodate users with high message traffic and those with low message traffic.

To accommodate users with high message traffic, Nasdaq is offering a connection that provides a constant 256K capacity, as opposed to a burst capacity feature. The monthly charge for

this option will be \$1,781. Members that submit lower amounts of message traffic will have the option to use a 56K constant connection. The monthly charge for this option will be \$712.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 15A of the Act,⁵ in general and with section 15A(b)(5) of the Act,⁶ in particular, in that it provides for the equitable allocation of reasonable fees among members. Nasdaq believes the fee reduction recognizes the changes in pricing that have occurred in the market and are designed to make the fees for Primex competitive with other trading venues. In addition, the fees for the new alternatives for connecting to Primex are based on the bandwidth provided and will be charged consistently to all members that choose the particular connection option.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Nasdaq has designated the proposed rule change as a fee change pursuant to section 19(b)(3)(A) of the Act and Rule 19b-4(f)(2) thereunder. Accordingly, the proposal will take effect upon filing with the Commission. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions

⁴ See Securities Exchange Act Release No. 45285 (January 15, 2002), 67 FR 3521 (January 24, 2002). In the filing establishing the original fee schedule for Primex, Nasdaq indicated it would not charge any fees during the initial few months Primex was operating, and that it would notify members through a Head Trader Alert when it would begin assessing fees. Nasdaq will begin assessing fees on August 1, 2002 according to the revised fee schedule, and will notify members accordingly. As such, fees were never charged under the original fee schedule.

⁵ 15 U.S.C. 78o-3.

⁶ 15 U.S.C. 78o-3.

should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR-NASD-2002-102 and should be submitted by September 11, 2002.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁷

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02-21321 Filed 8-20-02; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

(Release No. 34-46351; File No. SR-NASD-2002-110)

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the National Association of Securities Dealers, Inc. to Establish a New Registration Category for Proctors of In-Firm Delivery of the Regulatory Element of the Continuing Education Requirements

August 14, 2002.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on August 8, 2002, the National Association of Securities Dealers, Inc. ("NASD") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD proposes to establish NASD Rule 1043, a new registration category for proctors of in-firm delivery of the Regulatory Element of the NASD's continuing education requirements. The text of the proposed rule change is below. Proposed new language is in italics; proposed deletions are in brackets.

1040. Registration of Assistant Representatives [-Order Processing] *and Proctors*

1041. Registration Requirements for *Assistant Representatives*

(a) through (c) No change.

1042. Restrictions for *Assistant Representatives*

(a) through (c) No change.

1043. *Proctors of In-Firm Delivery of Regulatory Element*

(a) *Any person associated with a member seeking to be designated as a Proctor under Rule 1120(a)(6)(E) for the purposes of in-firm delivery of the Regulatory Element shall be required to be registered pursuant to Rule 1120(a)(6)(E)(iii), but shall not be required to pass a Qualification Examination.*

(b) *Any person associated with a member may be designated as a Proctor upon approval of an Application for Registration pursuant to Article V, Section 2 of NASD's By-Laws. Any person whose sole registration is as a Proctor pursuant to this Rule 1043 shall not be qualified to function in any other area requiring registration with NASD.*

(c) *Nothing in this Rule 1043 shall prohibit a person who is registered with NASD in any other capacity from also serving as a Proctor without being designated as such under these provisions.*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to establish a new registration category for proctors of in-firm delivery of the Regulatory Element of the NASD's continuing education requirements. The Regulatory Element requires all registered persons to participate in a prescribed computer-based training session within 120 days of their second registration anniversary date and every three years thereafter. The Regulatory Element focuses on compliance, regulatory and ethical standards.

NASD Rule 1120(a)(6) permits each member to administer the continuing education Regulatory Element program to their registered persons through a program delivered on the member's premises, provided that the member adheres to certain technology, administrative and regulatory standards. Among the requirements for in-firm delivery of the Regulatory Element is that the program sessions be proctored by an individual registered with a self-regulatory organization ("SRO") and supervised by a designated principal.

NASD Rule 1120(a)(6) was intended to ease the burden on members to meet their continuing education requirements. However, the NASD has observed that many members have chosen not to avail themselves of the in-firm delivery options. Members have informed the NASD that the registration requirement for proctors is one reason more members have not used in-firm delivery. Members either do not have registered persons available to act as proctors or do not want to commit resources needed to prepare a proctor for an exam-based registration. The Securities Industry/Regulatory Council on Continuing Education recommended that the SROs develop a means to allow proctors to be registered without taking a qualification examination.³ The NASD supported that recommendation and believes this proposed rule change is an effective solution that makes in-firm delivery a more attractive and efficient option for members while maintaining the integrity of the program.

Importantly, while the proposed rule change would permit proctors to be registered without an exam, it would still require the proctors to submit an

³ The Council includes 14 members representing a cross-section of securities firms and six SROs, including the NASD. The Council facilitates industry/regulatory coordination of the administration and future development of the Continuing Education Program.

⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

application for registration in accordance with NASD By-Laws. As such, proctors would be required to file a Form U-4, which provides detailed employment and disciplinary history so that the NASD can monitor the fitness of individuals to serve in that capacity. Any person whose sole registration is as a proctor under the proposed rule change would not be permitted to engage in any other activities requiring registration with the NASD. The proposal would not prohibit a person who is registered with the NASD in any other capacity from also serving as a proctor, as is permitted under existing rules.

2. Statutory Basis

The NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,⁴ which requires among other things, that the NASD's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The NASD believes that the proposed rule change will result in more efficient delivery of the NASD's continuing education requirements, while maintaining the integrity of the continuing education program.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing For Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NASD consents, the Commission will:

A. By order approve such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR-NASD-2002-110 and should be submitted by September 11, 2002.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁵

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02-21324 Filed 8-20-02; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-46356; File No. SR-NASD-2002-83]

Self-Regulatory Organizations; Order Granting Approval of Proposed Rule Change by the National Association of Securities Dealers, Inc. To Establish Fees Assessed on Non-Members for the Use of Computer-to-Computer Interface Transmission Control Protocol/Internet Protocol Lines That Use Message Queue Series Software

August 15, 2002.

On June 14, 2002, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities

Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to establish fees for non-members for the use of Computer-to-Computer Interface Transmission Control Protocol/Internet Protocol lines that use Message Queue Series ("MQ Series") software. The proposed rule change was published for notice and comment in the **Federal Register** on July 2, 2002.³ The Commission received no comments on the proposed rule change.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association⁴ and, in particular, the requirements of section 15A(b)(5),⁵ which requires the rules of a national securities association to provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility which the association operates or controls. The Commission believes Nasdaq's decision to charge firms that opt to use MQ Series a higher fee for lines that use the software than for comparable lines that do not, and to leave the existing fees unchanged for firms that do not use MQ Series, is reasonable.

It is therefore ordered, pursuant to section 19(b)(2) of the Act⁶, that the proposed rule change (SR-NASD-2002-83) be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁷

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02-21325 Filed 8-20-02; 8:45 am]

BILLING CODE 8010-01-P

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Securities Exchange Act Release No. 46112 (June 25, 2002), 67 FR 44488.

⁴ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

⁵ 15 U.S.C. 78o-3(b)(5).

⁶ 15 U.S.C. 78s(b)(2).

⁷ 17 CFR 200.30-3(a)(12).

⁴ 15 U.S.C. 78o-3(b)(6).

⁵ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-46360; File No. SR-PCX-2002-49]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. Amending PCX Rule 6.82(d)(2) in Order to Change the Percentage of Guaranteed Participation Afforded to Lead Market Makers

August 15, 2002.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4² thereunder, notice is hereby given that on July 25, 2002, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend PCX Rule 6.82(d)(2) in order to change the percentage of guaranteed participation afforded to Lead Market Makers ("LMMs").

The text of the proposed rule change appears below. New text is in italics; deletions are in brackets.

PACIFIC EXCHANGE, INC.

RULES OF THE BOARD OF GOVERNORS

Rule 6.82(a)-(c)—No change.

(d) Rights of Lead Market Makers:

(1)—No change.

(2) Guaranteed Participation. [Except as provided in subsections (A) and (B), below,] LMMs shall be allocated [50%] 40% participation (or such lesser percentage as the Options Allocation Committee may establish as a condition in allocating an issue to an LLM) in transactions occurring at their disseminated bids and/or offers in their allocated issue(s). LMM participation may be greater than [50%] 40% as a result of successful competition by means of "public outcry." LMMs at their own discretion may direct some or all of their participation to competing public orders in the crowd. Public orders placed in the book shall take priority pursuant to Exchange rules.

Oversight and enforcement shall be the responsibility of the OBO.

[(A) Multiply-traded Issues. If the average daily trading volume in a multiply-traded issue reaches 3,000 contracts at the Exchange during any three-calendar-month period (measured on a "rolling" three-calendar-month basis), and if:]

[(i) in the case of an issue traded by two options exchanges, the Exchange's monthly share of the total multi-exchange customer trading volume in the issue drops from above 70% to below 70%; or]

[(ii) in the case of an issue traded by three or more options exchanges, the Exchange's monthly share of the total multi-exchange customer trading volume in the issue drops from above 45% to below 45%; the Options Allocation Committee will evaluate the LMM's performance in that issue and, based on that evaluation, may reduce the LMM's guaranteed participation in that issue from 50% to 40%.]

[(B) Non multiply-traded Issues. If the average daily trading volume in a non-multiply-traded issue reaches 3,000 contracts at the Exchange during any three-calendar-month period (measured on a "rolling" three-calendar-month basis), the Options Allocation Committee will evaluate the LMM's performance in that issue and, based on that evaluation, may reduce the LMM's guaranteed participation in that issue from 50% to 25%.]

[(C) Return to Previous Levels of Guaranteed Participation. If the Options Allocation Committee has reduced an LMM's guaranteed participation in an issue pursuant to subsections (A) or (B) above, and average daily trading volume in the issue falls below 3,000 contracts at the Exchange during any three-calendar-month period (measured on a "rolling" three-calendar-month basis), the Options Allocation Committee will evaluate the LMM's performance in that issue and, based on that evaluation, may raise the LMM's guaranteed participation in that issue from 40% to 50% (in a multiply-traded issue) or from 25% to 50% (in a non-multiply-traded issue).]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, Exchange rules provide that LMMs may be allocated a maximum guaranteed participation of 50% in transactions occurring at their disseminated bid or offer.³ The Exchange has assessed guaranteed participation levels of other exchanges⁴ in relation to its own rules⁵ and determined that, in establishing a fair and orderly market, it is appropriate to decrease the LMM guaranteed from 50% to 40%. The Exchange also believes it is desirable to continue to grant the Options Allocation Committee ("OAC") the discretion to allocate less than 40% guaranteed participation on a case-by-case basis as a condition of allocating an issue to an LMM.⁶

The proposed rule also eliminates PCX Rules 6.82(d)(2)(A)-(C), which relate to guaranteed participation for LMMs with respect to multiply-traded and non multiply-traded issues. According to the Exchange, these rules were designed to measure LMM performance and allow the OAC to take

³ See PCX Rule 6.82(d)(2). The Rules of the PCX require that transactions of LMMs and Market Makers ("MMs") constitute a course of dealing that is reasonably calculated to contribute to the maintenance of a fair and orderly market. In furtherance of that goal, the Exchange has always required LMMs and MMs to make markets in options transactions and provide liquidity to the Exchange. LMMs have additional responsibilities that include, *inter alia*, the obligation to (1) assure that the disseminated market quotations are accurate; (2) determine formulas for generating automatically updated quotations and disclosing the elements of the formula to the members of the trading crowd; (3) be present at the trading post throughout every business day; (4) participate at all times in the automated execution system for each assigned option issue; (5) promote the exchange as a marketplace by assisting in meeting and educating market participants; and (6) maintain sufficient cash or liquid asset position.

⁴ Each of the other four options exchanges provides a tiered structure that guarantees specialists no more than 40% participation where there is more than one member on parity with the specialist's best bid or offer. See Chicago Board Options Exchange, Inc. Rule 8.87; Philadelphia Stock Exchange, Inc. Rule 1014(g); American Stock Exchange LLC Rule 950(d), Commentary .05; International Stock Exchange, Inc. Rule 713, Supplementary Material .01.

⁵ See, e.g., PCX Rule 6.47(b) (limiting LMM guaranteed participation in facilitation trades to 40%).

⁶ See Securities Exchange Act Release No. 45937 (May 15, 2002), 67 FR 36283 (May 23, 2002) (approving SR-PCX 2002-13 to allow the OAC to establish, as a condition in allocating an issue to an LMM, a lesser guaranteed percentage).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

market share into consideration when determining to reduce an LMM's guaranteed participation percentage in a particular issue. However, the Exchange believes that the process articulated in the rule is overly complicated and no longer serves its intended use, especially in light of this proposed rule to decrease guaranteed participation levels from 50% to 40%.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,⁷ in general, and furthers the objectives of section 6(b)(5),⁸ in particular, in that it is designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts and practices, and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act⁹ and subparagraph (f)(6) of Rule 19b-4¹⁰ thereunder because the Exchange has designated the proposed rule change as one that does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate; and the Exchange has given the Commission written notice of its intention to file the proposed rule change at least five business days prior to filing. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or

appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Acceleration of the operative date will permit the Exchange to promptly decrease the LMM guaranteed from 50% to 40%, affording Market Makers a greater opportunity to interact with orders and thereby enhancing competition on the Exchange. For these Commission designates the proposal to be become operative immediately.¹¹

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR-PCX-2002-49 and should be submitted by September 11, 2002.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.¹²

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 02-21320 Filed 8-20-02; 8:45 am]

BILLING CODE 8010-01-P

¹¹ For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

¹² 17 CFR 200.30-3(a)(12).

DEPARTMENT OF STATE

Bureau of Consular Affairs

[Public Notice 4103]

Registration for the Diversity Immigrant (DV-2004) Visa Program

ACTION: Notice of registration for the Diversity Immigrant Visa Program.

This public notice provides information on how to apply for the DV 2004 Program. This notice is issued pursuant to 22 CFR 42.33(b)(2) which implements sections 201(a)(3), 201(e), 203(c) and 204(a)(1)(I) of the Immigration and Nationality Act, as amended, (8 U.S.C. 1151(a)(3) and (e), 1153(c), and 1154(a)(1)(I)).

Entry Procedures for Immigrant Visas To Be Made Available in the DV Category During Fiscal Year 2004

Entries for DV-2004 must be received at one of the Kentucky Consular Center Mailing Addresses listed in this Notice between noon on Monday, October 7, 2002 and noon on Wednesday, November 6, 2002. Entries received before or after these dates will be disqualified regardless of when they are postmarked. Entries mailed to any address other than the Kentucky Consular Center addresses listed in this notice will be disqualified.

How Are Visas Apportioned?

Visas are apportioned among six geographic regions with a greater number of visas going to regions with lower rates of immigration, and no visas going to countries sending more than 50,000 immigrants to the U.S. in the past five years. Within each of the six regions, no one country may receive more than seven percent of the available Diversity Visas in one year. By law, the U.S. Diversity Visa Program makes available a maximum of 55,000 each year. However, the Nicaraguan and Central American Relief Act (NACARA) stipulates that beginning as early as DV-99 and for as long as necessary, 5,000 of the 55,000 annually-allocated diversity visas will be made available for use under the NACARA Program. This reduction began in DV-1999 and remains in effect for DV-2004.

For DV-2004, natives of the following are not eligible to apply because they sent more than 50,000 immigrants to the United States in the previous five years:

Canada
China (mainland-born)
Colombia
Dominican Republic
El Salvador
Haiti

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f)(6).

India
Jamaica
Mexico
Pakistan
Philippines
South Korea
United Kingdom (except Northern Ireland) and its dependent territories
Vietnam

(Persons born in Hong Kong SAR, Macau SAR and Taiwan are eligible.)

What Are the Requirements To Apply for the DV-2004 Visas?

Chargeability

To enter, an applicant must be able to claim nativity in an eligible country, and must meet either the education or training requirement of the DV program. Nativity in most cases is determined by the applicant's place of birth. However, if a person was born in an ineligible country but his/her spouse was born in an eligible country, such person can claim the spouse's country of birth rather than his/her own. Also, if a person was born in an ineligible country, but neither of his/her parents was born there or resided there at the time of the birth, such person may be able to claim nativity in one of the parents' country of birth.

Education or Training

To enter, an applicant must have either a high school education or its equivalent, defined in the U.S. as successful completion of a 12-year course of elementary and secondary education; or two years of work experience within the past five years in an occupation requiring at least two years of training or experience to perform. U.S. Department of Labor definitions, as indicated in the O*Net OnLine database, will apply. If a person does not meet these requirements, he/she should not submit an entry to the DV program.

Submitting an Entry

Only one entry may be submitted by or for each applicant during the registration period. Submission of more than one entry will disqualify the person. The applicant must personally sign the entry, in his/her native

alphabet. Neither an initialed signature nor block printing of the applicant's name will be accepted and will result in the disqualification of the entry. Failure of the applicant to personally sign his/her own entry will result in disqualification.

Completing the Entry

There is no specific form for the entry. Failure to provide all of the information listed below will disqualify the applicant. Simply use a plain sheet of paper and type or clearly print in the English (Roman) alphabet (preferably in the order listed below):

1. Full name, with the last (surname/family) name underlined:

Examples: Public, Sara Jane (or) Lopez, Juan Antonio.

2. Date and place of birth:

Date: Day, Month, Year.

Example: 15 November 1961.

Place: City/Town, District/County/Province, Country.

Example: Munich, Bavaria, Germany.

The name of the country should be that which is currently in use for the place where the applicant was born (For example, Slovenia, rather than Yugoslavia; Kazakhstan rather than Soviet Union.)

3. The applicant's native country if different from country of birth:

If the applicant is claiming nativity in a country other than his/her place of birth, this must be clearly indicated on the entry. This information must match with what is put on the upper left corner of the entry envelope. (See "MAILING THE ENTRY" below.) If an applicant is claiming nativity through spouse or parent, please indicate this on the entry. (See "REQUIREMENTS" section for more information on this item.)

4. Name, date and place of birth of the applicant's spouse and unmarried children who are under the age of 21 (other than children who are already U.S. citizens or lawful permanent residents). Include natural children, stepchildren, as well as all legally-adopted children. List spouse and children regardless of whether or not they reside with you and whether or not they will immigrate with you. (Failure

to provide ALL of this information will disqualify the applicant.) Note: married children and children 21 years or older will not qualify for the DV Program.

5. Full mailing address:

This must be clear and complete, as any communications will be sent there. A telephone number is optional, but useful.

6. Photographs. Attach a recent photograph, either black and white or in color, of the applicant, spouse and each child.

If photos do not conform to the following specifications, the entry will be disqualified:

The photo must be between 1½ by 1½ and 2 by 2 inches (37–50 mm) square in size, with the name and date of birth printed on the back of the applicant's, spouse's and child's photo.

The person photographed must be directly facing the camera. The head should not be tilted up, down or to the side and should cover about 50% of the area of the photo.

The person should be in front of a neutral, light-colored background.

The face must be in focus.

The person photographed may not wear a hat or dark glasses or other paraphernalia which detracts from the face.

Photos with the alien wearing head coverings or hats are only acceptable due to religious beliefs, and even then, may not obscure any portion of the face of the applicant.

Photos of applicants wearing tribal, military, airline or other headware not specifically religious in nature will not be accepted.

The photograph (not a photocopy) should be attached to the entry with clear tape—DO NOT use staples or paperclips, which can jam the mail processing equipment.

7. Signature: The entry will be disqualified if the entry is not personally signed by the applicant with the usual and customary signature in his/her native alphabet. Neither an initialed signature nor block printing of the applicant's name will be accepted.

BILLING CODE 4710-06-P

SAMPLE ENTRY

There is no specific format for the DV entry. The following is a sample entry, but other formats may be used. Failure to include all of the required information will disqualify the applicant.

1. FULL NAME:_____
LAST (surname/family)_____
FIRST**2. DATE OF BIRTH**_____
Day, Month, Year**PLACE OF BIRTH**_____
City/Town, District/County/Province, Country**3. APPLICANT'S NATIVE COUNTRY, IF DIFFERENT FROM COUNTRY OF BIRTH**_____
(See requirements above)**4. NAME, DATE AND PLACE OF BIRTH OF THE APPLICANT'S SPOUSE AND CHILDREN**_____
Name_____
Date of birth (day, month, year)_____
Place of birth_____
Name_____
Date of birth (day, month, year)_____
Place of birth_____
Name_____
Date of birth (day, month, year)_____
Place of birth

*Attach information on additional children as necessary.
Use the back of the page if there is insufficient space.*

5. FULL MAILING ADDRESS:_____

6. PHOTOGRAPH: *Attach recent photograph of the applicant, the applicant's spouse and all children. Individual separate photographs must be attached for the spouse and all children. Print the name and date of birth of each family member on the back of each photograph. Photos may be attached to the back of the entry if there is not enough room on the front*

7. SIGNATURE:

Failure to personally sign the entry will disqualify the applicant.

Mailing the Entry

Submit the entry by regular or airmail to the address matching the region of the applicant's country of nativity. Entries sent by express or priority mail, second day airmail, fax, hand, messenger, or any means requiring receipts or special handling will not be processed.

- The envelope must be between 6 and 10 inches (15 to 25 cm) long and 3½ and 4½ inches (9 to 11 cm) wide.
- Postcards are not acceptable.
- Envelopes inside express or oversized mail packets are not acceptable.
- In the upper left-hand corner of the envelope the applicant must write his/

her country of nativity, followed by the applicant's name and full return address, even if both are the same.

Failure to provide this information will disqualify the entry.

Mailing address: The mailing addresses for the six regions are as follows:

Africa	(Includes all countries on the African continent and adjacent islands):.	DV Program, Kentucky Consular Center, 1001 Visa Crest, Migrate, KY 41901–1000, USA.
Asia	(Extends from Israel to the Northern Pacific Islands, and includes Indonesia):.	DV Program Kentucky Consular Center, 2002 Visa Crest, Migrate, KY 41902–2000, USA.
Europe	(Extends from Greenland to Russia, and includes all countries of the former USSR).	DV Program Kentucky Consular Center, 3003 Visa Crest, Migrate, KY 41903–3000, USA.
South America/Central America/ Caribbean.	(Extends from Central America (Guatemala) and the Caribbean nations to Chile.).	DV Program Kentucky Consular Center, 4004 Visa Crest, Migrate, KY 41904–4000, USA.
Oceania	(Includes Australia, New Zealand, Papua New Guinea and all countries and islands of the South Pacific).	DV Program Kentucky Consular Center, 5005 Visa Crest, Migrate, KY 41905–5000, USA.
North America	(Includes the Bahamas)	DV Program Kentucky Consular Center, 6006 Visa Crest, Migrate, KY 41906–6000, USA.

EXAMPLE: An applicant who was born in Australia and now lives in France may submit one entry to

the appropriate address for Oceania; the envelope should look like this:

6" - 10" or 15 cm - 25 cm

**Australia
Applicant's Full Name
Street Address
City, Province, Postal Code
France**

**DV Program
Kentucky Consular Center
5005 Visa Crest
Migrate, KY 41905-5000, U.S.A.**

3 1/2 - 4 1/2"

or

9 cm - 11 cm

Selection

Every application received during the mail-in period and prepared in accordance with these instructions will have an equal random chance of being selected within its region. No outside service can legitimately improve an applicant's chances of being chosen or guarantee that an entry will win.

Important notice: In order to actually receive a visa, applicants selected in the random drawing must meet all eligibility requirements under U.S. law, including any applicable special processing requirements established in response to the events of September 11, 2001. These requirements may significantly increase the level of scrutiny required and time necessary for processing of applications for natives of some countries listed in this notice; particularly those where a higher level activity related to post-September 11 concerns has been indicated. These

include, but are not limited to, countries identified as state sponsors of terrorism. Processing of applications and issuance of diversity visas to successful applicants and their eligible family members **MUST** occur by September 30, 2004. Family members may not obtain diversity visas to follow to join the applicant in the U.S. after this date. There is **NO** initial fee, other than postage required to enter the DV–2004 program. The use of an outside intermediary or assistance to prepare a DV–2004 entry is entirely at the applicant's discretion. Qualified entries received directly from applicants or through intermediaries have equal chances of being selected by computer. There is no advantage to mailing early, or mailing from any particular locale. However, more than one application per person will disqualify the person from registration.

Determining 2004 DV Countries

The Immigration and Naturalization Service (INS) determines the DV regional limits for each year according to a formula specified in section 203(c) of the Immigration and Nationality Act. Natives of the following countries are eligible for the 2004 DV Program:

Africa

Algeria
Angola
Benin
Botswana
Burkina Faso
Burundi
Cameroon
Cape Verde
Central African Republic
Chad
Comoros
Congo
Congo, Democratic Republic of the
Cote D'Ivoire (Ivory Coast)
Djibouti

Egypt
 Equatorial Guinea
 Eritrea
 Ethiopia
 Gabon
 Gambia, The
 Ghana
 Guinea
 Guinea-Bissau
 Kenya
 Lesotho
 Liberia
 Libya
 Madagascar
 Malawi
 Mali
 Mauritania
 Mauritius
 Morocco
 Mozambique
 Namibia
 Niger
 Nigeria
 Rwanda
 Sao Tome and Principe
 Senegal
 Seychelles
 Sierra Leone
 Somalia
 South Africa
 Sudan
 Swaziland
 Tanzania
 Togo
 Tunisia
 Uganda
 Zambia
 Zimbabwe

Asia

Afghanistan
 Bahrain
 Bangladesh
 Bhutan
 Brunei
 Burma
 Cambodia
 Hong Kong Special Administrative Region
 Indonesia
 Iran
 Iraq
 Israel
 Japan
 Jordan
 Kuwait
 Laos
 Lebanon
 Macau Special Administrative Region
 Malaysia
 Maldives
 Mongolia
 Nepal
 North Korea
 Oman
 Qatar
 Saudi Arabia
 Singapore
 Sri Lanka

Syria
 Taiwan
 Thailand
 United Arab Emirates
 Yemen

Asia countries whose natives do not qualify for this year's diversity program: China (mainland-born), India, Pakistan, South Korea, Philippines, and Vietnam.

Europe

Albania
 Andorra
 Armenia
 Austria
 Azerbaijan
 Belarus
 Belgium
 Bosnia and Herzegovina
 Bulgaria
 Croatia
 Cyprus
 Czech Republic
 Denmark (including components and dependent areas overseas)
 Estonia
 Finland
 France (including components and dependent areas overseas)
 Georgia
 Germany
 Greece
 Hungary
 Iceland
 Ireland
 Italy
 Kazakhstan
 Kyrgyzstan
 Latvia
 Liechtenstein
 Lithuania
 Luxembourg
 Macedonia, the Former Yugoslav Republic of
 Malta
 Moldova
 Monaco
 Netherlands (including components and dependent areas overseas)
 Northern Ireland *
 Norway
 Poland
 Portugal
 Romania
 Russia
 San Marino
 Slovakia
 Slovenia
 Spain
 Sweden
 Switzerland
 Tajikistan
 Turkey
 Turkmenistan
 Ukraine
 Uzbekistan
 Vatican City
 Yugoslavia, Federal Republic of
 European countries whose natives do not qualify for this year's diversity

program: Great Britain (including Anguilla, Bermuda, British Virgin Islands, Cayman Islands, Falkland Islands, Gibraltar, Montserrat, Pitcairn, St. Helena, Turks and Caicos Islands.

***NOTE:** For the purposes of the diversity program only, Northern Ireland is treated separately and DOES qualify for this year's program.

North America

Bahamas, The
 In North America, natives of CANADA do not qualify for this year's diversity program.

Oceania

Australia (including components and dependent areas overseas)
 Fiji
 Kiribati
 Marshall Islands
 Micronesia, Federated States of
 Nauru
 New Zealand (including components and dependent areas overseas)
 Palau
 Papua New Guinea
 Samoa
 Solomon Islands
 Tonga
 Tuvalu
 Vanuatu

South American, Central American, and the Caribbean

Antigua and Barbuda
 Argentina
 Barbados
 Belize
 Bolivia
 Brazil
 Chile
 Costa Rica
 Cuba
 Dominica
 Ecuador
 Grenada
 Guatemala
 Guyana
 Honduras
 Nicaragua
 Panama
 Paraguay
 Peru
 St. Kitts and Nevis
 St. Lucia
 St. Vincent and the Grenadines
 Suriname
 Trinidad and Tobago
 Uruguay
 Venezuela

Countries in this region whose natives do not qualify for this year's diversity program: Colombia, Dominican Republic, El Salvador, Haiti, Jamaica and Mexico.

Notifying Successful Entrants

Only successful entrants will be notified. They will be notified by mail

between April and July of 2003 at the address listed on their entry. Successful entrants will also be sent instructions on how to apply for an immigrant visa, including information on the fee for immigrant visas and a separate visa lottery surcharge. Successful entrants must complete the immigrant visa application process and meet all eligibility requirements under U.S. law to be issued a visa.

Being selected in the DV Lottery does not automatically guarantee issuance of a visa, even if the applicant is qualified, because the number of entries selected and registered is greater than the number of immigrant visas available. Those selected will, therefore, need to complete and file their immigrant visa applications quickly. Once all the diversity visas have been issued or on September 30, 2004, whichever is sooner, the DV Program for Fiscal Year 2004 will end.

Obtaining Instructions on Entering the DV Lottery

Interested persons may call (202) 331-7199, which describes the various means to obtain further details on entering the DV-2004 program. Applicants overseas may contact the nearest U.S. embassy or consulate for instructions on the DV lottery. DV information is also available in the Visa Bulletin, on the Internet at <http://travel.state.gov> or via the Consular Affairs automated fax at (202) 647-3000 (code 1103). Calls to the automated fax service must be made from a fax machine using the receiver or voice option of the caller's fax equipment.

George Lannon,

Acting Assistant Secretary for Consular Affairs, Department of State.

[FR Doc. 02-21411 Filed 8-20-02; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement; Pottawattamie County, IA, Douglas County, NE

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for improving the freeway system for Interstate-80 (I-80), I-29, and I-480 in the City of Council Bluffs, Pottawattamie County, Iowa, and the

City of Omaha, Douglas County, Nebraska.

FOR FURTHER INFORMATION CONTACT:

Rebecca Hiatt, Operations Engineer, FHWA, 105 6th Street, Ames, IA 50010-6337, (515) 233-7321. James P. Rost, Director, Office of Location and Environment, Iowa Department of Transportation, 800 Lincoln Way, Ames, IA 50010, (515) 239-1798.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may reach the **Federal Register's** home page at: <http://www.nara.gov/fedreg> and the Government Printing Office's database at: <http://www.access.gpo.gov/nara>.

Background

The FHWA, in cooperation with the Iowa Department of Transportation, will prepare an environmental impact statement (EIS) for the proposed Council Bluffs Interstate System Improvement Project including improvements to I-80, I-29, and I-480. The system deficiencies noted in an earlier needs study (conducted by the Metropolitan Planning Organization and the City of Council Bluffs in April 1999) included deteriorated roadways and bridges, reduced travel efficiency, substandard roadway geometry, and safety issues. The proposed system improvements include approximately 18 mainline-miles of interstate, and 16 interchanges (3 system, 13 service). The project area includes Interstate 80 from near the 24th Street interchange in the City of Omaha, Nebraska, east to U.S. Hwy 6 (Kanesville Blvd) just northeast of the City of Council Bluffs, Iowa. The project also includes: Interstate 29, from just south of Iowa Hwy 92 and U.S. Hwy 275 south of Council Bluffs, and north to Iowa Hwy 192 (16th Street) just north of Council Bluffs; Interstate 480 from the Missouri River Bridge (on the Nebraska side) to Interstate 29 at the Broadway interchange in Council Bluffs; studies of the Missouri River crossings; and an underpass of the Union Pacific mainline.

Due to the size of the system and the multi-year/multi-project approach, a tiered EIS process will be conducted. A Tier 1 EIS will be prepared to determine the preferred set of long-range improvements for the I-80, I-29, and I-480 freeway system. The EIS will consider a broad range of alternatives including no action, reconstruction of

the existing alignment, and improvements to transportation system management, transportation demand management, transit, and cross-town corridors. Following the conclusion of the Tier 1 EIS, preliminary engineering, in-depth environmental studies, and Tier 2 environmental documents (EIS, environmental assessment (EA), or categorical exclusion (CE)) will be completed for individual projects as appropriate.

Letters describing the proposed action and soliciting comments have been sent to appropriate federal, state, and local agencies, and to private organizations and citizens who are known to be interested in this proposed project.

A scoping meeting for identifying significant issues to be addressed in the environmental impact statement will be held on September 12, 2002 from 4 to 7 p.m. at the Best Western Crossroads of the Bluffs at 2216 27th Avenue (I-80 and 24th Street), Council Bluffs, Iowa.

In addition to the scoping meeting, a series of public meetings and a public hearing on the draft EIS will be held in the City of Council Bluffs, Iowa, during 2002, 2003 and 2004. Public notice will be given of the time and place of the public meetings and public hearing. The draft EIS will be available for public and agency review and comment prior to the public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the Iowa Department of Transportation or FHWA at the address provided under the caption **FOR FURTHER INFORMATION CONTACT**.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation of Federal programs and activities apply to this program.)

(Authority: 23 U.S.C. 315; 49 CFR 1.48)

Bobby W. Blackmon,

Division Administrator.

[FR Doc. 02-21214 Filed 8-20-02; 8:45 am]

BILLING CODE 4910-22-U

MARITIME ADMINISTRATION

[Docket Number: MARAD-2002-13156]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel DESTINY'S WINDS.

SUMMARY: As authorized by Pub. L. 105-383, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a description of the proposed service, is listed below. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines that in accordance with Pub. L. 105-383 and MARAD's regulations at 46 CFR Part 388 (65 FR 6905; February 11, 2000) that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels, a waiver will not be granted.

DATES: Submit comments on or before September 20, 2002.

ADDRESSES: Comments should refer to docket number MARAD-2002-13156. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. DOT Dockets, Room PL-401, Department of Transportation, 400 7th St., SW., Washington, DC 20590-0001. You may also send comments electronically via the Internet at <http://dmses.dot.gov/submit/>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Kathleen Dunn, U.S. Department of Transportation, Maritime Administration, MAR-832 Room 7201, 400 Seventh Street, SW., Washington, DC 20590. Telephone 202-366-2307.

SUPPLEMENTARY INFORMATION: Title V of Pub. L. 105-383 provides authority to the Secretary of Transportation to administratively waive the U.S.-build requirements of the Jones Act, and other statutes, for small commercial passenger vessels (no more than 12 passengers). This authority has been delegated to the Maritime Administration per 49 CFR § 1.66, Delegations to the Maritime Administrator, as amended. By this notice, MARAD is publishing information on a vessel for which a request for a U.S.-build waiver has been

received, and for which MARAD requests comments from interested parties. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Vessel Proposed for Waiver of the U.S.-build Requirement

(1) Name of vessel and owner for which waiver is requested. *Name of vessel:* DESTINY'S WINDS. *Owner:* Hugh C. Garver.

(2) Size, capacity and tonnage of vessel. *According to the applicant:* "The vessel is 46' long, 14' breadth, with a gross tonnage of 16 and a net tonnage of 14."

(3) Intended use for vessel, including geographic region of intended operation and trade. *According to the applicant:* "I intend to use the vessel for charter work throughout the coastline of Florida. If possible, I would extend the area to include New Orleans to Savannah, GA."

(4) Date and Place of construction and (if applicable) rebuilding. *Date of construction:* 1980. *Place of construction:* La Rochelle, France.

(5) A statement on the impact this waiver will have on other commercial passenger vessel operators. *According to the applicant:* "To my knowledge, there are no long range charter sail operators in the area of Destin, Florida. In researching the feasibility of such an operation, I could only find five advertised charter operators within the geographic area I have requested."

(6) A statement on the impact this waiver will have on U.S. shipyards. *According to the applicant:* "Throughout the coastline, there are many facilities that one can get immediate towing and repair service. They could help me if necessary and any work would be of benefit to them should I need their services."

Dated: August 16, 2002.

By order of the Maritime Administrator.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. 02-21299 Filed 8-20-02; 8:45 am]

BILLING CODE 4910-81-P

MARITIME ADMINISTRATION

[Docket Number: MARAD-2002-13155]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel WILD FLOWER.

SUMMARY: As authorized by Pub. L. 105-383, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a description of the proposed service, is listed below. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines that in accordance with Pub. L. 105-383 and MARAD's regulations at 46 CFR part 388 (65 FR 6905; February 11, 2000) that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels, a waiver will not be granted.

DATES: Submit comments on or before September 20, 2002.

ADDRESSES: Comments should refer to docket number MARAD-2002-13155. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. DOT Dockets, Room PL-401, Department of Transportation, 400 7th St., SW., Washington, DC 20590-0001. You may also send comments electronically via the Internet at <http://dmses.dot.gov/submit/>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Kathleen Dunn, U.S. Department of Transportation, Maritime Administration, MAR-832 Room 7201, 400 Seventh Street, SW., Washington, DC 20590. Telephone 202-366-2307.

SUPPLEMENTARY INFORMATION: Title V of Pub. L. 105-383 provides authority to the Secretary of Transportation to administratively waive the U.S.-build requirements of the Jones Act, and other statutes, for small commercial passenger vessels (no more than 12 passengers). This authority has been delegated to the Maritime Administration per 49 CFR § 1.66, Delegations to the Maritime Administrator, as amended. By this notice, MARAD is publishing information on a vessel for which a request for a U.S.-build waiver has been

received, and for which MARAD requests comments from interested parties. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD'S regulations at 46 CFR Part 388.

Vessel Proposed for Waiver of the U.S.-build Requirement

(1) Name of vessel and owner for which waiver is requested. *Name of vessel:* WILD FLOWER. *Owner:* Wild Flower Enterprises.

(2) Size, capacity and tonnage of vessel. According to the applicant: "The vessel is 64'8" long, her breadth is 17'5" and her depth is 7'. Her gross tonnage is 29 GRT and her net tonnage is 26 NRT."

(3) Intended use for vessel, including geographic region of intended operation and trade. According to the applicant: "The vessel is unique in the crewed chartering industry in that . . . she charters only for two passengers . . . The average charter lasts for one week (food and wine included in the price) with the boat on anchor or on a mooring overnight . . . The geographic region of intended operation is in the waters from New York City through the waters of Maine."

(4) Date and Place of construction and (if applicable) rebuilding. *Date of construction:* 1985. *Place of construction:* Taiwan, ROC.

(5) A statement on the impact this waiver will have on other commercial

passenger vessel operators. According to the applicant: "Since there are currently no vessels in the intended area of operation over 55' that charter exclusively for two passengers, there can be no impact, if the waiver is granted on other commercial vessel operators."

(6) A statement on the impact this waiver will have on U.S. shipyards. According to the applicant: "If the application is granted, the vessel will be in the United States in the appropriate season and can have her yearly hauling and bottom painting done at U.S. shipyards. This can only have a positive impact on these shipyards."

Dated: August 16, 2002.

By order of the Maritime Administrator.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. 02-21300 Filed 8-20-02; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF THE TREASURY

[Treasury Order Number 150-39]

Delegation of Authority to Act as Competent or Taxation Authority for Possessions of the United States

July 17, 2002.

1. *Purpose.* The purpose of this Order is to formalize the authority of the Commissioner of Internal Revenue to act as the competent authority or taxation authority under tax coordination agreements and tax implementation agreements with the possessions of the United States, with the responsibility for coordination and liaison of tax

administration issues involving the possessions of the United States.

2. *Delegation.* The authority of the Secretary of the Treasury to act as competent authority or taxation authority with regard to tax implementation and coordination agreements that are entered into with the possessions of the United States is hereby delegated to the Commissioner of Internal Revenue. The authority of the Commissioner of Internal Revenue to provide for the administration of the United States internal revenue laws in the possessions of the United States (including administration of the aforesaid tax agreements) remains in effect.

3. *Redelegation.* The Commissioner may redelegate this authority in writing to any officer or employee of the Internal Revenue Service.

4. *Ratification.* To the extent that any action heretofore taken by the Commissioner of Internal Revenue or his delegate consistent with the delegation set forth in this Order may require ratification, such action is hereby affirmed and ratified.

Authorities

a. IRC § 7803(a)(2).

b. Subtitle G of Title XII of the Tax Reform Act of 1986, sections 1271 to 1277 of Pub. Law 99-514, 100 Stat. 2085, 2591-2602.

6. *Office of Primary Interest.* Commissioner of Internal Revenue.

Paul H. O'Neill,

Secretary of the Treasury.

[FR Doc. 02-21259 Filed 8-20-02; 8:45 am]

BILLING CODE 4810-25-P

Corrections

Federal Register

Vol. 67, No. 162

Wednesday, August 21, 2002

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002-SW-22-AD; Amendment 39-12835; AD 2002-08-54]

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron Canada Model 222, 222B, 222U, and 230 Helicopters

Correction

In rule document 02-19486 beginning on page 50793 in the issue of Tuesday,

August 6, 2002 make the following correction:

§39.13 [Corrected]

On page 50794, in §39.13, in the table, under the “ Model” heading, in the third entry “(3)” should read “(3) 230 ”.

[FR Doc. C2-19486 Filed 8-20-02; 8:45 am]

BILLING CODE 1505-01-D



Federal Register

**Wednesday,
August 21, 2002**

Part II

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

**Endangered and Threatened Wildlife and
Plants; Designation of Critical Habitat for
the Topeka Shiner; Proposed Rule**

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018-AI20

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Topeka Shiner**AGENCY:** Fish and Wildlife Service, Interior.**ACTION:** Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose designation of critical habitat pursuant to the Endangered Species Act of 1973, as amended (Act), for the Topeka shiner (*Notropis topeka*). This proposal is made in response to a court settlement in *Biodiversity Legal Foundation et al. v. Ralph Morganweck et al.* C00-D-1180, committing the Service to submit for publication in the **Federal Register** a proposal to withdraw the existing "not prudent" critical habitat determination together with a new proposed critical habitat determination for the Topeka shiner by August 13, 2002. We are proposing to designate as critical habitat a total of 186 stream segments, representing 3,765.9 kilometers (2,340 miles) of stream in the States of Iowa, Kansas, Minnesota, Nebraska, and South Dakota. Proposed critical habitat includes portions of the North Raccoon, Boone, and Rock River watersheds in Iowa; the Kansas, Big Blue, Smoky Hill, and Cottonwood River watersheds in Kansas; the Rock and Big Sioux River watersheds in Minnesota; and the Big Sioux, Vermillion, and James River watersheds in South Dakota. If this proposed rule is finalized, Federal agencies proposing actions that may affect the areas designated as critical habitat must consult with the Service on the effects of the proposed actions, pursuant to section 7(a)(2) of the Act. A draft Economic Analysis will be prepared in the near future and made available for public comment. We will specify the availability of the draft Economic Analysis and subsequent reopening of the comment period in local and regional newspapers in the range of the species and through a notice in the **Federal Register**.

DATES: We will consider all comments on the proposed rule received from interested parties by October 21, 2002. We will hold public meetings in—Manhattan, KS, on September 4, 2002; Bethany, MO, on September 5, 2002; Fort Dodge, IA, on September 9, 2002; Pipestone, MN, on September 10, 2002; Sioux Falls, SD on September 11, 2002;

and, Madison, NE, on September 12, 2002. We will start all meetings promptly at 6 p.m. and end them no later than 9 p.m. (See "Public Hearings and Meetings" section for times and locations.)

ADDRESSES: Send your comments on the proposed rule to the Kansas Ecological Services Field Office, U.S. Fish and Wildlife Service, 315 Houston Street, Suite E, Manhattan, KS 66502. The complete file for the proposed rule will be available for public inspection, by appointment, during normal business hours at the above address. Copies of the proposed rule are available by writing to the above address or by connecting to the Service internet web site at "<http://mountain-prairie.fws.gov/topekashiner/ch>."

FOR FURTHER INFORMATION CONTACT: Vernon Tabor, Kansas Ecological Services Field Office, at the above address; telephone (785) 539-3474, facsimile (785) 539-8567.

SUPPLEMENTARY INFORMATION:**Background**

The Topeka shiner is a small, stout minnow, not exceeding 75 millimeters (3 inches) in total length. The head is short with a small, moderately oblique mouth. The eye diameter is equal to or slightly longer than the snout. The dorsal fin is large, with the height more than one half the predorsal length of the fish, originating over the leading edge of the pectoral fins. Dorsal and pelvic fins each contain eight rays. The anal and pectoral fins contain 7 and 13 rays respectively, and there are 32 to 37 lateral line scales. Dorsally the body is olivaceous (olive-green), with a distinct dark stripe preceding the dorsal fin. A dusky stripe is exhibited along the entire longitudinal length of the lateral line. The scales above this line are darkly outlined with pigment, appearing cross-hatched. Below the lateral line the body lacks pigment, appearing silvery-white. A distinct chevron-like spot exists at the base of the caudal fin (Cross 1967; Pflieger 1975; U.S. Fish and Wildlife Service 1993).

The Topeka shiner was first described by C.H. Gilbert in 1884, using specimens captured from Shunganunga Creek, Shawnee County, Kansas (Gilbert 1884), a tributary to the Kansas River. The Topeka shiner is 1 of 83 species within the genus *Notropis* (Robins et al. 1991), all in North America. The genus is within the minnow family (*Cyprinidae*).

The Topeka shiner is characteristic of small to mid-size prairie streams with relatively high water quality and cool to moderate temperatures. Many of these

streams exhibit perennial flow; however, some become intermittent during summer or periods of prolonged drought. At times when surface flows cease, pool levels and moderate water temperatures are maintained by percolation through the streambed or groundwater seepage. The predominant substrate types within these streams are gravel, cobble, and sand; however, bedrock and clay hardpan overlain by a layer of silt are not uncommon (Minckley and Cross 1959). Recently in northern portions of the species' range, the Topeka shiner has been found to exist at some stream sites with degraded water quality and habitat quality, characterized by moderately high turbidity and thick deposits of fine sediments, respectively (Hatch, University of Minnesota, pers. comm. 2000; Berry, South Dakota State University, pers. comm. 2000). At present, it is unknown whether the species utilizes these sites year-round or seasonally, or moves through these areas in an attempt to disperse from core habitat areas.

In the late 1990s, the Topeka shiner was discovered to inhabit a number of off-channel sites in Minnesota and Iowa, primarily cut-off channels and oxbows that are seasonally flooded (Hatch, pers. comm. 1999; Menzel, Iowa State University, pers. comm. 1999). It is speculated that a common factor of these off-channel sites is a connection with the water table, enabling water quality, particularly temperature and dissolved oxygen concentrations, to stay within the tolerance levels of the species during hot, dry periods. It also is suggested that the ground water contact prevents total freeze-out of these pools during winter.

Topeka shiners most often occur in pool and run areas of streams, seldom being found in riffles. They are most often pelagic (living in open water) in nature, occurring in mid-water and surface areas, and are primarily considered a schooling fish. Occasionally individuals of this species have been found in larger streams, downstream of known populations (Cross 1967; Pflieger 1975; Tabor, U.S. Fish and Wildlife Service 1998).

Historically, the Topeka shiner was widespread and abundant throughout small to mid-size streams of the central prairie regions of the United States. The Topeka shiner's historic range includes portions of Iowa, Kansas, Minnesota, Missouri, Nebraska, and South Dakota. Stream basins within the range historically occupied by the Topeka shiner include the Des Moines, Raccoon, Boone, Missouri, Big Sioux, Cedar, Shell Rock, Rock, and Iowa

Basins in Iowa; the Arkansas, Kansas, Big Blue, Saline, Solomon, Republican, Smoky Hill, Wakarusa, Cottonwood, Nemaha, and Blue Basins in Kansas; the Des Moines, Cedar, Big Sioux, and Rock Basins in Minnesota; the Missouri, Grand, Lamine, Chariton, Des Moines, Loutre, Middle, Hundred and Two, and Blue Basins in Missouri; the Big Blue, Elkhorn, Missouri, and Loup Basins in Nebraska; and the Big Sioux, Vermillion, and James Basins in South Dakota. The known geographic range (watershed area where the species was known to occur) of the Topeka shiner has been reduced by approximately 90 percent. The number of historically known collection sites (documented in the literature or by museum specimens) of Topeka shiner has been reduced by approximately 70 percent, with approximately 50 percent of this decline occurring within the last 40–50 years. The species now primarily exists in isolated population complexes (adjoining stream segments) and individual isolated stream reaches.

The Topeka shiner is impacted by habitat destruction, degradation, modification, and fragmentation resulting from siltation, reduced water quality, tributary impoundment, stream channelization, in-stream gravel mining, and changes in stream hydrology. The species also can be impacted by introduced predaceous fishes. Additional information on the biology and status of the Topeka shiner can be found in the December 15, 1998, final listing determination (63 FR 69008). Biological factors relevant to the species' habitat needs are discussed in the Primary Constituent Elements portion of this proposed rule.

Previous Federal Action

In 1990 the Service's Kansas Field Office began a status review of the Topeka shiner using data collected from stream sampling activities and information requested from knowledgeable individuals and agencies, including State fish and wildlife conservation agencies, State health and pollution control agencies, colleges and universities, and other Service offices. The Topeka shiner first received listing consideration when the species was included in the Animal Candidate Review for Listing as Endangered or Threatened Species, as a category 2 candidate species, published in the **Federal Register** (56 FR 58816) on November 21, 1991. Category 2 candidate species were those species for which information in the possession of the Service indicated that a proposal to list the species as endangered or threatened was possibly appropriate,

but sufficient data on biological vulnerability and threats were not currently available to support proposed rules for listing. A status report, dated February 16, 1993 (Service 1993), was subsequently prepared concerning the species. In the November 15, 1994, Animal Candidate Review for Listing as Endangered or Threatened Species, published in the **Federal Register** (59 FR 58999), the Topeka shiner was reclassified as a category 1 candidate species. Category 1 candidates comprised taxa for which the Service had substantial information on biological vulnerability and threats to support proposals to list the taxa as endangered or threatened. We have since discontinued the category 1 and category 2 designations for candidates and have established a new policy defining candidate species. Candidate species are currently defined as those species for which the Service has sufficient information on file detailing biological vulnerability and threats to support issuance of a proposed rule to list as threatened or endangered, but issuance of the proposed rule is precluded by other listing actions. In the February 28, 1996, Review of Plant and Animal Taxa That Are Candidates for Listing as Endangered or Threatened Species, published in the **Federal Register** (61 FR 7596), the Topeka shiner was reclassified as a candidate species.

We published a proposed rule to list the Topeka shiner as endangered in the **Federal Register** on October 24, 1997 (62 FR 55381). Included in the proposed rule was notification of the opening of a 60-day public comment period and request for public hearings. The comment period was open from October 24, 1997, to December 23, 1997. Four public hearings were held from January 26–29, 1998, across the species' range. A notice to reopen the public comment period was published in the **Federal Register** (62 FR 67324) to accommodate the hearings. This comment period was open from January 12, 1998, to February 9, 1998. We published the final rule listing the Topeka shiner as an endangered species on December 15, 1998 (63 FR 69008). The effective date of the listing was January 14, 1999. We did not designate critical habitat at the time of listing, as we determined that designation of critical habitat was not prudent.

In early 1999, we assembled the Topeka Shiner Recovery Team. The team is composed of species experts from academia and industry, State natural resource agency personnel with knowledge of the species, and Fish and Wildlife Service staff. Seven team

meetings were held between 1999 to 2001, with the task of developing a draft recovery plan for the species. The Service is reviewing this draft and hopes its findings can be used as a basis for its proposed recovery plan.

In an April 4, 2001, court settlement of the case, *Biodiversity Legal Foundation et al. v. Ralph Morganweck et al.*, C00–D–1180, we agreed to reconsider our prudency determination and, if prudent, propose critical habitat for the Topeka shiner by August 13, 2002, and to finalize our decision on critical habitat by August 13, 2003.

Critical Habitat

Critical habitat is defined in section 3(5)(A) of the Act as—(I) the specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. The term “conservation,” as defined in section 3(3) of the Act, means “to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this Act are no longer necessary.”

Critical habitat receives protection under section 7 of the Act through the prohibition against destruction or adverse modification of critical habitat with regard to actions carried out, funded, or authorized by a Federal agency. Section 7 also requires conferences with the Service on Federal actions that are likely to result in the destruction or adverse modification of proposed critical habitat. In our regulations at 50 CFR 402.02, we define destruction or adverse modification as “a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical.” Aside from the added protection that may be provided under section 7, the Act does not provide other forms of protection to lands designated as critical habitat. Because consultation under section 7 of the Act does not apply to activities on private or other non-Federal lands that

do not involve a Federal nexus, critical habitat designation would not result in any regulatory requirement for these actions.

To be included in a critical habitat designation, the habitat must first be "essential to the conservation of the species." Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species (*i.e.*, areas in which the primary constituent elements, as defined at 50 CFR 424.12(b), are found).

Section 4 requires that we designate critical habitat at the time of listing and based on what we know at the time of designation. When we designate critical habitat at the time of listing or under short court-ordered deadlines, we will often not have sufficient information to identify all areas of critical habitat. We are required, nevertheless, to make a decision and thus must base our designations on what, at the time of designation, we know to be critical habitat.

In accordance with sections 3(5)(C) of the Act, not all areas that can be occupied by a species will be designated critical habitat. Within the geographic area occupied by the species we designate only areas currently known to be essential. Essential areas should already have the features and habitat characteristics that are necessary to conserve the species. We will not speculate about what areas might be found to be essential if better information becomes available, or what areas may become essential over time. If the information available at the time of designation does not show that an area provides essential life cycle needs of the species, then the area should not be included in the critical habitat designation. We will not designate areas within the geographic area occupied by the species unless at least one of the primary constituent elements, as defined at 50 CFR 424.12(b), is present. Moreover, areas occupied by certain known populations of the Topeka shiner have not been proposed as critical habitat. For example, we did not propose critical habitat for some small scattered populations or habitats in areas highly impacted by human development.

Our regulations state, "The Secretary shall designate as critical habitat areas outside the geographical area presently occupied by a species only when a designation limited to its present range would be inadequate to ensure the conservation of the species" (50 CFR 424.12(e)). Based on the best available science and commercial data, there

appears to be no foundation upon which to make a determination that the conservation needs of the Topeka shiner require designation of critical habitat outside of the geographic area occupied by the species, so we have not proposed to designate critical habitat outside of the geographic area believed to be occupied.

Our Policy on Information Standards Under the Endangered Species Act, published in the **Federal Register** on July 1, 1994 (59 FR 34271), provides criteria, procedures, and guidance to ensure decisions made by the Service represent the best scientific and commercial data available. It requires Service biologists, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information should be the listing package for the species. Additional information may be obtained from a recovery plan, articles in peer-reviewed journals, conservation plans developed by States, Tribes, and counties, scientific status surveys and studies, and biological assessments or other unpublished materials, and expert opinion or personal knowledge.

Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize designation of critical habitat may not include all habitat eventually determined as necessary to recover the species. For these reasons, all should understand that critical habitat designations do not signal that habitat outside the designation is unimportant or may not be required for recovery. Areas outside the critical habitat designation will continue to be subject to conservation actions that may be implemented under section 7(a)(1) of the Act, and the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the section 9 take prohibition, as determined on the basis of the best available information at the time of the action. Federally funded or assisted projects affecting listed species outside their designated critical habitat areas may still result in likely-to-jeopardize findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts, if new information available to these

planning efforts calls for a different outcome.

Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas to propose as critical habitat we are required to base critical habitat determinations on the best scientific and commercial data available and to consider physical and biological features (primary constituent elements) that are essential to conservation of the species, and that may require special management considerations and protection. These physical and biological features include, but are not limited to—(1) Space for individual and population growth, and for normal behavior; (2) food, water, air, light, minerals, or other nutritional or physiological requirements; (3) cover or shelter; (4) sites for breeding, reproduction, rearing (or development) of offspring; and (5) habitats protected from disturbance or that are representative of the historic geographical and ecological distributions of a species.

The following studies involving the habitat requirements, life history, and population biology of Topeka shiner serve as the best science available in establishing the primary constituent elements listed below—Barber 1986; Blausey 2001; Cross 1967; Cross 1970; Cross and Collins 1975; Cross and Collins 1995; Deacon and Metcalf 1961; Gelwicks and Bruenderman 1996; Hatch 2001; Hatch and Besaw 2001; Katula 1998; Kerns 1983; Leopold *et al.* 1992; Michels 2000; Michl and Peters 1993; Minckley and Cross 1959; Pflieger 1975; Pflieger 1997; Rosgen 1996; Shranke *et al.* 2001; Stark *et al.* 1999; U.S. Fish and Wildlife Service 1993; Wall *et al.* 2001.

Given the large geographic range the species historically occupied, and the varying habitats used by the different life-history stages, describing specific values or conditions for each of these habitat features is not always possible. However, the following discussion summarizes the biological and habitat requirements of the Topeka shiner relevant to identifying the primary constituent elements of its critical habitat.

Topeka shiners are typically found in small, low order, prairie streams with good water quality, relatively cool temperatures, and low fish diversity (Minckley and Cross 1959; Cross 1967; Barber 1986; Cross and Collins 1995; Pflieger 1997; Blausey 2001). Although Topeka shiners can tolerate a range of water temperatures, cooler, spring-maintained systems are considered

optimum (Cross and Collins 1995; Pflieger 1997). These streams generally maintain perennial flow but may become intermittent during summer or periods of drought. Evermann and Cox (1896) reported on surveys from the Nebraska portion of the Big Blue River watershed, and noted that Topeka shiners occurred in "pond-like, isolated portions of streams which dry up in parts of their course during dry weather." Minckley and Cross (1959) found Topeka shiners "almost exclusively in quiet, open pools of small, clear streams that drain upland prairies." They also noted that when these streams approach intermittency the "pools are maintained at fairly stable levels by percolation through the gravel or by springs." Similar habitat characteristics are described for populations in Missouri by Pflieger (1997). In South Dakota, Blausey (2001) found that runs were the dominant habitat type associated with Topeka shiner presence, although higher densities of the species were collected in pools. While characteristic of pools with stable water levels, the Topeka shiner appears to be well adapted to periodic drought conditions common to prairie streams. For example, Kerns (1983) found that even though mortality of several fish species was high in desiccating pools, juvenile Topeka shiners seemed especially drought-resistant.

In Kansas, Missouri, and South Dakota, Topeka shiners typically occur in streams with clean gravel, cobble, or sand bottoms (Pflieger 1975; Kerns 1983; Barber 1986; Cross and Collins 1995; Pflieger 1997; Blausey 2001). However, bedrock and clay hardpan covered by a thin layer of silt are not uncommon (Minckley and Cross 1959). In western Kansas pools containing Topeka shiners, Stark *et al.* (1999) determined the primary substrate to be coarse sand overlain by silt and detritus. Similarly, Michl and Peters (1993) reported the collection of Topeka shiners from a Nebraska stream having a sand and detritus substrate. While main channel areas may be typical of Kansas, Missouri, and South Dakota populations, Topeka shiners in Minnesota and Iowa appear more abundant in off-channel oxbows and side-channels than in the main channels (Menzel pers. comm. 1999; Hatch 2001). These seasonally flooded habitats also appear to have a connection with the water table, enabling temperature and dissolved oxygen to stay within tolerance levels of the species during dry, hot periods. It also suggests that the groundwater connection may prevent

complete freezing of these pools in winter. Groundwater availability was a primary predictor of Topeka shiner presence in South Dakota (Blausey 2001). While we have recently found the species in some stream sites with excessive sedimentation, it is unknown whether the species uses these locations year-round, for portions of the year, or occupy these areas during periods of dispersal. In much of the range of Topeka shiner, moderate-sized mainstem streams likely provide occasional dispersal corridors for the species (Cunningham, Eco-Centrics, Inc., Omaha, Nebraska, pers. comm. 1999; Menzel pers. comm. 2001). In most cases these larger streams do not provide habitat conditions suitable for the species to complete its necessary life cycle requirements, but in the Iowa and Minnesota range of the species oxbow and other off-channel habitats adjacent to these mainstems do provide these requirements (Menzel pers. comm. 2001; Hatch 2001). In these cases, the primary constituent elements of critical habitat are present in the off-channel areas, but not in the larger mainstem streams themselves, even though they likely provide corridors for dispersion to other areas of suitable habitat.

Topeka shiners are short-lived species, rarely surviving to their third summer (Minckley and Cross 1959; Cross 1967; Kerns 1983; Cross and Collins 1995; Pflieger 1997; Hatch 2001). The species typically matures at 12–14 months of age (Kerns 1983; Cross and Collins 1995; Pflieger 1997). Based on ovarian development, Hatch (2001) suggested that Topeka shiners are multiple-clutch spawners. Topeka shiners spawn in pool habitats, over green sunfish (*Lepomis cyanellus*) and orangespotted sunfish (*Lepomis humilis*) nests, from late May to August in Kansas and Missouri (Kerns 1983; Cross and Collins 1995; Pflieger 1997). Stark *et al.* (1999) observed Topeka shiners spawning on the periphery of green sunfish nests and suggested that the habitats provided by these nests are important to the reproductive success of Topeka shiners. These same authors reported aggregations of Topeka shiners in close association with fathead minnow (*Pimephales promelas*) and orangespotted sunfish nests, but no spawning activities were observed. In Minnesota, Hatch (2001) found that Topeka shiners use rubble, boulder, and concrete rip-rap at the margins of pools and slow runs. Several authors have reported the defense of small territories by breeding male Topeka shiners (Kerns 1983, Pflieger 1997, Katula 1998, Stark *et al.* 1999, Hatch 2001). In Jack Creek,

Chase County, Kansas, Mammoliti (Kansas Department of Wildlife and Parks, pers. comm. 1999) observed two male Topeka shiners defending a longear sunfish (*Lepomis megalotis*) nest as the male sunfish loafed nearby. Other authors have noted upstream movement as reproductive behavior in Topeka shiners (Minckley and Cross 1959, Kerns 1983, Barber 1986).

The Topeka shiner is primarily a schooling fish and found throughout the water column. Pflieger (1997) noted that the species schooled with other cyprinids in mid-water or near the surface. Other studies have reported Topeka shiners schooling in the lower portion of the water column with central stonerollers (*Camptostoma anomalum*) (Kerns 1983, Stark *et al.* 1999). While typical of small, headwater streams, occasionally the species has been captured in larger streams, downstream of known populations. Barber (1986) noted variation in mobility within a population of Topeka shiner based on sex and age class. In the spring, as precipitation and water temperatures increased, adult males tended to move upstream or downstream. In many instances, the fish moved back to their original pool. Young-of-the-year fish tended to move downstream in the fall. Others have reported displacement of fish downstream during periods of high flow (Cross, University of Kansas, pers. comm. 1994; Tabor pers. comm. 1994). Although it is evident that the species has some capacity to disperse, at present the degree of dispersal and the species' ability to "tributary hop" is unknown. It has been suggested that populations found in short, direct tributaries to the Missouri River were evidence of a historic dispersal eastward by "tributary hopping." However, Deacon and Metcalf (1961) found the Topeka shiner to be one of several fishes with a low capacity for dispersal following drought conditions. In addition, Michels (2000) conducted a range-wide genetic analysis of different populations of Topeka shiner and suggested that successful migration, even between adjacent populations, is rare and that movement over long distances is unlikely.

Earlier researchers (Kerns 1983, Cross and Collins 1995) reported that Topeka shiners are benthic insectivores that feed primarily on midges (chironomids), true flies (dipterans), and mayflies (ephemeropterans), with zooplankton (cladocerans and copepods) also contributing to their diet. More recent studies have found Topeka shiner feeding at a variety of trophic levels and on diverse foods. Stark *et al.* (1999) observed Topeka shiners consuming

eggs from fathead minnow nests in Willow Creek, Wallace County, Kansas. In Minnesota, food included several kinds of zooplankton, a variety of immature aquatic insects, larval fish, algal and vascular plant matter, including seed capsules (Hatch and Besaw 1998). These authors suggested that Topeka shiners function both as benthic and nektonic feeders, and propose that the species also may feed from the surfaces of aquatic plants.

We determine the primary constituent elements associated with critical habitat for Topeka shiner to be:

1. Streams most often with permanent flow, but that can become intermittent during dry periods;

2. Side channel pools and oxbows either seasonally connected to a stream or maintained by groundwater inputs, at a surface elevation equal to or lower than the bank-full discharge stream elevation. The bankfull discharge is the flow at which water begins leaving the channel and flowing into the floodplain; this level is generally attained every 1 to 2 years. Bankfull discharge, while a function of the size of the stream, is a fairly constant feature related to the formation, maintenance, and dimensions of the stream channel;

3. Streams and side channel pools with water quality necessary for unimpaired behavior, growth, and viability of all life stages. The water quality components can vary seasonally and include—temperature (1 to 30°C/centigrade), total suspended solids (0 to 2000 ppm), conductivity (100 to 800 mhos), dissolved oxygen (4 ppm or greater), pH (7.0 to 9.0), and other chemical characteristics;

4. Living and spawning areas for adult Topeka shiner with pools or runs with water velocities less than 0.5 meters/second (approx. 20 inches/second) and depths ranging from 0.1 to 2.0 meters (approximately 4 to 80 inches);

5. Living areas for juvenile Topeka shiner with water velocities less than 0.5 meters/second (approx. 20 inches/second) with depths less than 0.25 meters (approx. 10 inches) and moderate amounts of instream aquatic cover, such as woody debris, overhanging terrestrial vegetation, and aquatic plants;

6. Sand, gravel, cobble, and silt substrates with amounts of fine sediment and substrate embeddedness that allows for nest building and maintenance of nests and eggs by native Lepomis sunfishes (green sunfish, orangespotted sunfish, longear sunfish) and Topeka shiner as necessary for reproduction, unimpaired behavior, growth, and viability of all life stages;

7. An adequate terrestrial, semiaquatic, and aquatic invertebrate food base that allows for unimpaired growth, reproduction, and survival of all life stages;

8. A hydrologic regime capable of forming, maintaining, or restoring the flow periodicity, channel morphology, fish community composition, off-channel habitats, and habitat components described in the other primary constituent elements; and

9. Few or no nonnative predatory or competitive nonnative species present.

The areas we are proposing for designation as critical habitat for Topeka shiner provide the above primary constituent elements essential for the conservation of the species. The proposed areas require special management considerations or protection to ensure their contribution to the conservation of the species.

Proposed Critical Habitat Designation

In proposing critical habitat for Topeka shiner, we reviewed the overall approach to the conservation of the species undertaken by local, State, Tribal, and Federal agencies and private individuals and organizations since the species' listing in 1998. We also considered the measures identified as necessary for recovery, as outlined in the species' preliminary draft recovery plan. Additionally, we solicited information and recommendations from knowledgeable biologists and members of the Topeka Shiner Recovery Team. We also reviewed the available information pertaining to habitat requirements of the species received during the listing process.

TABLE 1.—NUMBER OF STREAM SEGMENTS AND TOTAL STREAM MILEAGE PROPOSED FOR DESIGNATION AS CRITICAL HABITAT FOR TOPEKA SHINER BY STATE

State	No. of stream segments proposed by State	Total stream mileage proposed by State
Iowa	25	225
Kansas	63	587
Minnesota	57	605
Nebraska	1	6
South Dakota	40	917
Total	186	2,340

TABLE 2.—NUMBER OF STREAM SEGMENTS AND TOTAL STREAM MILEAGE PROPOSED FOR DESIGNATION AS CRITICAL HABITAT FOR TOPEKA SHINER BY COUNTY

County	Number of stream segments proposed by county	Stream mileage proposed by county
Iowa:		
Calhoun	8	68
Carroll	2	7
Dallas	3	3
Greene	8	87
Hamilton	1	1
Lyon	3	16
Osceola	1	5
Sac	4	12
Webster	1	9
Wright	3	16
Kansas:		
Butler	1	5
Chase	27	200
Dickinson ...	4	49
Geary	7	62
Greenwood ...	2	7
Marion	1	9
Marshall	2	22
Morris	6	22
Pottawatomie	1	5
Riley	4	44
Shawnee	1	18
Wabaunsee ...	15	136
Wallace	1	9
Minnesota:		
Lincoln	4	27
Murray	2	19
Nobles	14	115
Pipestone ...	21	196
Rock	25	247
Nebraska:		
Madison	1	6
South Dakota:		
Aurora	1	27
Beadle	3	98
Brookings ...	6	106
Clay	2	29
Davison	4	63
Deuel	2	36
Hamlin	1	8
Hanson	3	48
Hutchinson ...	6	66
Lincoln	3	41
McCook	2	47
Miner	2	31
Minnehaha ...	6	102
Moody	5	63
Turner	6	151

Note: Many stream segments occur in more than one county, thus inflating the total number per State, if totaled.

Due to the need for additional information on the species, its habitats, restoration potential, possible unknown isolated occurrences, and other factors, interim criteria for downlisting and delisting were set forth in a preliminary draft recovery plan now under review by the Service. The recovery team agreed that even though much

information on the species is known, it would be prudent to develop interim recovery criteria, as opposed to final criteria at the time the plan was developed. It also was agreed by the recovery team that the interim recovery criteria would later be adjusted to reflect new information, as it becomes available, solidifying final recovery criteria. The primary information need identified in coming to this decision was information on stream and watershed conditions within unoccupied historic range, in reference to the potential for reintroduction and reestablishment of the species in these areas. Additionally, there was the need for more information on the species' range, particularly in Nebraska and parts of Iowa, where isolated, remnant populations of Topeka shiner might be discovered, possibly affecting recovery goals. If previously unknown populations were found in these areas, this would avoid the need for reintroduction in these areas. Reintroduction and successful reestablishment is most often viewed as being more difficult than maintenance and enhancement of existing populations and habitat. The interim recovery criteria recommend protection of existing populations, enhancement and restoration of habitats occupied by depleted populations, and reintroduction and reestablishment of the species into unoccupied streams within the historical range. Since information and data are lacking on conditions of the watersheds and instream habitat in unoccupied historic range of the species, we do not propose habitat in these areas, even though we recognize that the interim recovery criteria includes reintroduction and reestablishment of Topeka shiner to these areas. We are proposing stream segments occupied by Topeka shiner, and some stream segments with no records of capture for the species that connect with occupied stream segments. These connecting stream segments possess the primary constituent elements necessary for proposal, and likely harbor the species during some flow conditions. Examples of habitat use of this type include, upstream movement during high flows or wet periods, and downstream habitat use during dry periods or periods of extended drought. Due to this consideration, we regard all stream segments proposed for critical habitat as within the geographical area occupied by the species.

Within the geographic area occupied by the species, we are designating only areas currently known to be "essential

to the conservation of the species." Critical habitat should already have, or have the potential for developing in the near future, many or all of the features and habitat characteristics that are necessary to sustain the species. We do not speculate about what areas might be found to be essential if better information were available, or what areas may become essential over time. If information available at the time of designation does not show an area provides essential support for a species at any phase of its life cycle, then the area should not be included in the critical habitat designation. Within the geographic area occupied by the species, we will not designate areas that do not now have the primary constituent elements that provide essential life cycle needs of the species, as defined at 50 CFR 424.12(b). Furthermore, we recognize designation of critical habitat may not include all habitat eventually determined as necessary to recover the species. For these reasons, areas outside the critical habitat designation will continue to be subject to conservation actions that may be implemented under section 7(a)(1) and the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the section 9 take prohibition, as determined on the basis of the best available information at the time of the action. We specifically anticipate that federally funded or assisted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to those planning efforts calls for a different outcome.

The proposed critical habitat described below constitutes our best assessment of areas needed for the conservation of Topeka shiner and is based on the best scientific and commercial information available. The proposed areas are essential to the conservation of the species because they currently support populations of Topeka shiner or provide critical links or corridors to other habitat for the species. The stream segments proposed for designation as critical habitat in this proposed rule are consistent with the preliminary draft recovery plan's first recovery of the species will be recognized as achieved when all

naturally occurring populations within primary and secondary recovery units are determined to be stable or increasing over a period of 10 years.

Important considerations in selection of areas proposed in this rule include factors specific to each geographic area, watershed and stream segment, such as stream size and length, connectivity, and habitat diversity, as well as range-wide recovery considerations, such as genetic diversity and representation of major portions of the species' historical range. The proposed critical habitat reflects the need for habitat complexes and individual stream reaches of sufficient size to provide habitat for Topeka shiner populations large enough to be self-sustaining over time, despite fluctuations in local conditions.

Habitat complexes contain interconnected waters so that Topeka shiners can move between areas, at least during certain flows or seasons. The ability of the fish to repopulate areas where they are now depleted or extirpated is vital to the species' conservation. Some complexes may include stream reaches with minimal instream habitat, but which provide migration corridors for Topeka shiners. These corridors play a vital role in the dispersal of the species and the overall functioning of the aquatic ecosystem and, therefore, the integrity of upstream and downstream habitats.

The proposed designation includes representatives of all known populations of the species so as to conserve and protect genetic diversity within the species. Information on the Topeka shiner indicates a high degree of genetic differentiation among many of the remnant populations (Michels 2000), making conservation of as many of these populations as possible important to efforts to preserve genetic diversity.

Uncertainty on upstream and downstream distributional limits of some populations may result in areas of occupied habitat being excluded from the designation. Additionally, there are streams with some recent association with Topeka shiners that may not be proposed for designation. These could include streams with records of one-time captures of Topeka shiner; streams for which habitat conditions are unknown; streams with unprecise, generalized, or questionable capture locations; and streams with severely altered habitat, lacking the primary constituent elements (e.g., drainage ditches).

Our determination of which stream segments to propose for designation used the best scientific information and data available. We began the process by

compiling information on the species and its habitat to create draft maps of potentially suitable stream reaches. We then consulted species experts in academia, members of the Topeka Shiner Recovery Team, and biologists from State natural resource and fish and wildlife agencies familiar with the species or the watersheds in areas with the Topeka shiner. We also consulted biologists from other Service offices in the species' range. We asked for their review of the stream reaches identified on the draft maps, and for any suggested changes or additions.

Factors considered in determining specific stream segments included—streams with occupancy and habitat information for the species; stream reaches with all or some of the primary constituent elements for Topeka shiners, including those able to attain them in the foreseeable future; habitat models; information on the species' ecology and biology; stream morphology and hydrology information; regional habitat use by the species, such as use of side-channel pools in Iowa, Minnesota, and the Big Sioux drainage in South Dakota; major habitat alterations, such as channelization and dams; and information on the mobility of Topeka shiner in reference to connectivity of adjacent stream reaches, and to home range and dispersal characteristics. Information and suggested changes provided by the individuals and agencies who reviewed the draft maps were carefully considered and implemented where they were consistent with the Service's criteria for designating critical habitat.

The proposed designation includes 186 stream segments, encompassing 3,765.9 kilometers (2,340 miles) of streams, including adjacent off-channel pool habitats in Iowa, Minnesota, and the Big Sioux River watershed of South Dakota. The stream segments are within 11 major watersheds in the States of Iowa, Kansas, Minnesota, Nebraska, and South Dakota. These 186 proposed stream segments encompass 23 stream complexes (2 or more connecting stream segments) and 18 individual, isolated streams. No habitat is proposed for Missouri (see Exclusions from Critical Habitat section below).

Proposed critical habitat includes the stream channels within the identified stream reaches and off-channel pools and oxbows in the Minnesota, Iowa, and the Big Sioux River portion of the South Dakota range. Side channel pools and oxbows that are proposed for designation are typically either seasonally connected to a stream or have waters maintained by groundwater inputs. The defining stream elevation

for determining the lateral extent of proposed critical habitat in stream channels and off-channel or oxbow pools is the elevation equal to the bankfull discharge stream elevation. The bankfull discharge is the flow at which water begins leaving the channel and flowing into the floodplain (Rosgen 1996). This level is generally attained every 1 to 2 years (Leopold *et al.* 1992). Bankfull discharge, while a function of the size of the stream, is a fairly constant feature related to the formation, maintenance, and dimensions of the stream channel (Rosgen 1996).

We propose the following areas for designation as critical habitat. These areas—(1) Are currently considered occupied or provide critical links or corridors between occupied habitats and/or potentially occupied habitat; (2) provide all or some of the primary constituent elements essential to the conservation of the species; and (3) may require special management considerations or protection. (See the Regulation Promulgation section of this rule for legal descriptions and maps of the boundaries.)

Iowa

Raccoon River Watershed

1. *North Raccoon River Complex (19 stream segments), Calhoun, Carroll, Dallas, Greene, Sac, and Webster Counties, Iowa.* Multiple tributary streams and some of their adjacent off-channel pool habitats in this complex have recent collection records for Topeka shiners. While some habitat in these tributaries has been altered (primarily by channelization and sedimentation), current habitat conditions provide most or all of the primary constituent elements consistent with designation as critical habitat. Off-channel pool habitats adjacent to the mainstem of the North Raccoon River also have been discovered to be Topeka shiner habitat, and we propose these areas as well. However, records of Topeka shiners are lacking from the mainstem of the North Raccoon River itself. It is likely that the mainstem provides an important dispersal corridor for the species between tributary streams and off-channel pools adjacent to the mainstem, particularly during high flow events, but the habitat components within the mainstem itself do not provide the primary constituent elements necessary for proposing it for designation as critical habitat. We are proposing 19 stream segments within portions of the following tributaries and their qualifying, adjacent off-channel habitat for designation—Indian Creek,

Ditch 57, and Outlet Creek; Camp Creek and West Fork Camp Creek; Prairie Creek; Lake Creek; Purgatory Creek; Cedar Creek, West Cedar Creek, and East Cedar Creek; Short Creek; Hardin Creek; Buttrick Creek, West Buttrick Creek, and East Buttrick Creek; and Elm Branch and Swan Lake Branch. Additionally, qualifying off-channel pool habitat (as described in the section on Primary Constituent Elements) adjacent to the mainstem of the North Raccoon River is proposed for designation.

Boone River Watershed

2. *Eagle Creek (one stream segment), Hamilton and Wright Counties, Iowa.* Eagle Creek has several recent collections of Topeka shiner even though a large portion of its upper basin has been severely altered by stream channelization and drainage ditch construction. The lower reaches of Eagle Creek still retain much of its natural stream morphology, including meanders and pool habitat. We propose the lower reach of Eagle Creek and qualifying, adjacent off-channel pool habitats for designation. The upper, channelized, portions of Eagle Creek are not proposed for designation.

3. *Ditch 3 and Ditch 19 Complex (two stream segments), Wright County, Iowa.* The proposed reach of Ditch 3 extends from its confluence with the Boone River, upstream to the Humboldt County line. Ditch 19 also extends upstream from its confluence with Ditch 3 to the Humboldt County line. While the general map descriptions of these streams are termed “ditches” due to channelization activities in the past, both streams have reestablished much of their natural morphology and instream habitat conditions in the recent past, including meanders and pool habitats. Habitat components within these streams are consistent with the Primary Constituent Elements necessary for designation as critical habitat downstream from the Humboldt County line. Topeka shiners have been recently captured from both streams. Qualifying off-channel pool habitat also is proposed. Habitat upstream from the Humboldt County line is highly modified by channelization and is not proposed for designation.

Rock River Watershed

4. *Rock River Complex (two stream segments in Iowa), Lyon County, Iowa.* The Rock River Complex is comprised of 2 stream segments in Iowa and 28 stream segments in Minnesota. Topeka shiners have recently been captured throughout much of the Rock River watershed, both from streams and adjacent off-channel pools and oxbows.

We propose the reach of the Rock River from its confluence with Kanaranzi Creek upstream to the border with Minnesota, and Kanaranzi Creek from the confluence with the Rock River upstream to the Minnesota border. Adjacent, qualifying off-channel pool habitats along both stream segments also are proposed.

5. *Little Rock River Complex (one stream segment in Iowa), Lyon and Osceola Counties, Iowa.* The Little Rock River Complex is comprised of one stream segment in Iowa and two stream segments in Minnesota. Topeka shiners have recently been captured in portions of the Little Rock River watershed, both from streams and adjacent off-channel pools and oxbows. We propose the reach of the Little Rock River from near the town of Little Rock, Iowa, upstream to the Minnesota border, including qualifying, adjacent off-channel pool habitat.

Kansas

Big Sioux River Watershed

1. *Medary Creek Complex (two stream segments in Minnesota), Lincoln County, Minnesota.* This complex is comprised of two stream segments in Minnesota and three in South Dakota. Topeka shiners recently have been captured from several localities in this complex. We propose portions of Medary Creek and an unnamed tributary, and adjacent off-channel pool habitat for designation.

2. *Flandreau Creek Complex (four stream segments in Minnesota), Lincoln and Pipestone Counties, Minnesota.* This complex is comprised of four stream segments in Minnesota and one in South Dakota. Topeka shiners have been recently captured from several localities in this complex. We proposed portions of Flandreau Creek and an unnamed tributary, East Branch Flandreau Creek, Willow Creek, and adjacent off-channel pool habitat for designation.

3. *Split Rock/Pipestone/Beaver Creek Complex (18 stream segments in Minnesota), Pipestone and Rock Counties, Minnesota.* This complex is comprised of 18 stream segments in Minnesota and 7 in South Dakota. The streams and some of their adjacent off-channel pool habitats in this complex have recent collection records for the Topeka shiner. While some habitat in these tributary streams has been altered, primarily by channelization and sedimentation, current habitat conditions provide most or all of the primary constituent elements.

Cottonwood River Watershed

1. *Fox Creek Complex (three stream segments), Chase County, Kansas.* This complex is characterized by high quality aquatic habitat. Recent collection records exist from two unnamed tributaries to Fox Creek. We propose for designation the lower reach of Fox Creek from near Strong City, Kansas, upstream through the Tallgrass Prairie National Preserve, an area managed by the U.S. National Park Service, and two unnamed tributary streams in the Preserve.

2. *Diamond Creek Complex (eight stream segments), Chase and Morris Counties, Kansas.* This complex is generally characterized by high-quality aquatic habitat draining large tracts of tallgrass prairie. However, an upstream portion of the basin has been largely converted to rowcropping, with a subsequent decline in aquatic habitat quality. Recent collection records exist in many of the streams draining the upland prairie habitat. We propose portions of the following streams for designation—Diamond Creek from near its confluence with the Cottonwood River, upstream to the confluence with Sixmile Creek; Gannon Creek and an unnamed tributary; Mulvane Creek; Schaffer Creek and four unnamed tributaries; Dodds Creek; Sixmile Creek; Mulberry Creek and an unnamed tributary; and an unnamed direct tributary to the Cottonwood River immediately adjacent to, and downstream from, the lower reach of Diamond Creek.

3. *Middle Creek Complex (three stream segments), Chase County, Kansas.* This complex is generally characterized by high-quality aquatic habitat draining large tracts of tallgrass prairie. However, portions of the western sub-basins have been converted to rowcropping. There also are several tributary streams that have had intensive dam construction, resulting in major changes to habitat and fish communities. Following dam development in the Stribby Creek drainage of the Middle Creek Basin, Topeka shiners disappeared both upstream and downstream from the impoundments. Recent collection records only exist from two streams—Collett Creek, and an unnamed tributary to Middle Creek in the lower portion of the basin. We propose portions of the following streams for designation—the lower reach of Middle Creek and two adjoining unnamed tributaries; and Collett Creek.

4. *South Fork of the Cottonwood River (South Fork) Complex (15 stream segments), Butler, Chase, and*

Greenwood Counties, Kansas. This complex is characterized by high-quality aquatic habitat draining large tracts of tallgrass prairie. Many of the streams within this watershed have capture records for the species. There are several tributaries, including one site on the upper mainstem, that were dammed just prior to the Topeka shiner being listed as an endangered species. There have been no recent surveys along these streams to determine if Topeka shiner populations have been affected; however, the species persists in other portions of the watershed. We propose portions of the following streams for designation—the mainstem of the South Fork of the Cottonwood River from its confluence with the Cottonwood River, upstream to near its headwaters; Sharpes Creek; Rock Creek; Den Creek; Crocker Creek and an unnamed tributary; Mercer Creek and two unnamed tributaries; Jack Creek; Thurman Creek and an unnamed tributary; Little Cedar Creek; Shaw Creek; and Bloody Creek, a direct tributary to the Cottonwood River immediately downstream from the South Fork of the Cottonwood River confluence with the mainstem.

5. *Mud Creek (one stream segment), Marion County, Kansas.* This watershed is characterized by a mosaic of prairie and cropland. We propose one stream segment in the upper portion of the Mud Creek watershed.

Kansas River Watershed

6. *Mill Creek Complex (14 stream segments), Wabaunsee County, Kansas.* This complex is generally characterized by high-quality aquatic habitat draining large tracts of tallgrass prairie. However, much of the floodplain areas of mainstem Mill Creek and several of its tributaries have been converted to cropland. This conversion, likely in combination with intensive instream gravel dredging, has resulted in headcutting, bank erosion, and the loss of riparian vegetation. There is a moderate level of tributary dam development, primarily in the headwaters of the basin, and there are riparian and instream areas where cattle are over-wintered, resulting in large inputs of nutrients to the streams during periods of heavy rainfall. Recent collection records of Topeka shiner exist for many of the streams in the basin, but their abundance appears to be declining when compared with capture records from the 1950s–1970s. We propose portions of the following streams for designation—Mill Creek upstream from State Highway 30; West Branch Mill Creek; South Branch Mill Creek; East Branch Mill Creek; Mulberry Creek;

Spring Creek (a direct tributary to mainstem Mill Creek); Kuenzli Creek; Paw Paw Creek; Pretty Creek; Hendricks Creek; Loire Creek; Illinois Creek; Spring Creek (a tributary to West Branch Mill Creek); and Nehring Creek.

7. *Mission Creek (one stream segment), Shawnee and Wabaunsee Counties, Kansas.* This stream is characterized by good aquatic habitat draining tallgrass prairie uplands and a cultivated floodplain. Riparian conditions are good and generally appear stable. We propose the reach of Mission Creek upstream from Interstate Highway 70.

8. *Deep Creek Complex (two stream segments), Riley County, Kansas.* The Deep Creek Complex is characterized by high-quality aquatic habitat draining tallgrass prairie uplands and a partially cultivated floodplain. Riparian conditions are good and generally appear stable except for upstream reaches of Deep Creek where intensive instream gravel mining is occurring, resulting in severe stream bank erosion and headcutting. Recent records of Topeka shiner exist from the Pilsbury Crossing area of Deep Creek, and the lower and mid-reaches of School Creek. We propose portions of the following streams for designation—Deep Creek from near its confluence with the Kansas River, upstream to Interstate Highway 70; and approximately the downstream one-half of School Creek.

9. *Wildcat Creek Complex (two stream segments), Riley County, Kansas.* The Wildcat Creek Complex is composed of two stream segments and drains a variety of landscapes including cultivated cropland, tallgrass prairie uplands, and woodlands. The lower portion of the proposed downstream reach drains areas of suburban Manhattan, Kansas. This suburban reach retains good habitat quality including pool/riffle complexes, meanders, and stable riparian conditions. Riparian conditions throughout the proposed reaches are generally in good condition. Wildcat Creek's aquatic habitat is moderately impacted by sediment and nutrient inputs from upstream sources. We propose a stream segment near Riley, Kansas, and a reach from near Keats to Manhattan, Kansas. We are proposing to exclude the reach of Wildcat Creek flowing through the Fort Riley Military Installation (see Exclusions from Critical Habitat section).

10. *Clarks Creek Complex (five stream segments), Geary County, Kansas.* These streams can generally be characterized as having good aquatic habitat draining tallgrass prairie uplands and a partially cultivated floodplain. Riparian

conditions are good and generally appear stable. Instream gravel mining occurs at variable levels in this complex. Capture records of Topeka shiner within this complex are recent. We propose portions of the following streams for designation—a mid-basin reach of Clarks Creek; Thomas Creek; Davis Creek; Dry Creek; and West Branch Dry Creek.

11. *Lyon Creek Complex (five stream segments), Geary and Dickinson Counties, Kansas.* The Lyon Creek Complex is composed of five stream segments that drain variable landscapes. Much of the basin, particularly the western portion, drains a mosaic of prairie uplands and croplands. Instream habitat conditions vary, with some stream reaches degraded by heavy sediment and nutrient loading. Watershed impoundments and ponds are a major feature in several of the sub-drainages of this watershed, particularly in the southeastern portion of the Lyon Creek watershed. We propose portions of the following streams for designation—the lower and mid-basin reaches of Lyon Creek; Rock Springs Creek; Carry Creek and an unnamed tributary; and West Branch Lyon Creek.

12. *Walnut Creek (one stream segment), Big Blue River Watershed, Riley County, Kansas.* Walnut Creek is characterized by good quality aquatic habitat. However, this reach at times has limited downstream refugia due to the backup of floodwaters from Tuttle Creek Reservoir. The proposed reach is upstream from the flood pool of the reservoir.

Big Blue River Watershed

13. *Clear Fork Creek (one stream segment), Marshall and Pottawatomie Counties, Kansas.* Clear Fork Creek is a tributary to the Black Vermillion River. Their confluence is in the flood pool of Tuttle Creek Reservoir. This stream is characterized by good aquatic habitat draining primarily tallgrass prairie uplands and a partially cultivated floodplain. Riparian conditions are good and generally appear stable. An apparently stable population of Topeka shiners exists within its mid-to upper reaches. Clear Fork Creek is a relatively long stream upstream of the flood pool of the reservoir, with the upper and middle reaches proposed for designation.

14. *North Elm Creek (one stream segment), Marshall County, Kansas.* North Elm Creek is a direct tributary to the Big Blue River near the Kansas/Nebraska border. This stream is characterized by moderately degraded instream habitat in many places, as a result of heavy sediment loading. The

watershed is predominantly cropland. However, there are known areas within this stream with springs and seeps which likely contribute to the species' continuing existence in this locale. The proposed reach of North Elm Creek is upstream from its confluence with the Big Blue River to near its headwaters.

Smoky Hill River Watershed

15. *Willow Creek (one stream segment), Wallace County, Kansas.* The available habitat in this stream is a series of spring-fed pools with good water quality, in a watershed drained by shortgrass prairie and areas of dryland and irrigated cropping. Good land stewardship on the property surrounding the permanent pools, in combination with the spring inflows, are likely the primary factors in the continuing conservation of this population.

Minnesota

Big Sioux River Watershed

1. *Medary Creek Complex (two stream segments in Minnesota), Lincoln County, Minnesota.* This complex is comprised of two stream segments in Minnesota and three in South Dakota. Topeka shiners recently have been captured from several localities in this complex. We propose portions of Medary Creek and an unnamed tributary, and adjacent off-channel pool habitat for designation.

2. *Flandreau Creek Complex (four stream segments in Minnesota), Lincoln and Pipestone Counties, Minnesota.* This complex is comprised of four stream segments in Minnesota and one in South Dakota. Topeka shiners have been recently captured from several localities in this complex. We propose portions of Flandreau Creek and an unnamed tributary, East Branch Flandreau Creek, Willow Creek, and adjacent off-channel pool habitat for designation.

3. *Split Rock/Pipestone/Beaver Creek Complex (18 stream segments in Minnesota), Pipestone and Rock Counties, Minnesota.* This complex is comprised of 18 stream segments in Minnesota and 7 in South Dakota. The streams and some of their adjacent off-channel pool habitats in this complex have recent collection records for the Topeka shiner. While some habitat in these tributary streams has been altered, primarily by channelization and sedimentation, current habitat conditions provide most or all of the primary constituent elements consistent with designation as critical habitat. We propose for designation portions of—Pipestone Creek and two unnamed

tributaries; North Branch Pipestone Creek and an unnamed tributary; and Split Rock Creek and five unnamed tributaries; Beaver Creek and two unnamed tributaries; Little Beaver Creek; Springwater Creek; and adjacent off-channel pool habitat.

Rock River Watershed

4. *Rock River Complex (28 stream segments in Minnesota), Murray, Nobles, Pipestone, and Rock Counties, Minnesota.* The Rock River Complex is comprised of 28 stream segments in Minnesota and 2 stream segments in Iowa. Many streams in this complex have been impacted by channelization and sedimentation to varying degrees. These streams are characterized by predominantly natural morphology, instream pools, and a number of off-channel and oxbow pools, with some short reaches of channelization. Topeka shiners have recently been captured throughout much of the Rock River watershed, from both streams and adjacent off-channel pools and oxbows. We propose portions of the following stream reaches, along with adjacent off-channel pool habitat for designation—the Rock River from Minnesota/Iowa border, upstream to near Holland, Minnesota, and six unnamed tributaries; East Branch Rock River and an unnamed tributary; Kanaranzi Creek, East Branch Kanaranzi Creek, and three unnamed tributaries; Norwegian Creek and an unnamed tributary; Ash Creek; Elk Creek and an unnamed tributary; Champepadan Creek and three unnamed tributaries; Mound Creek; Poplar Creek and an unnamed tributary; and Chanarambie Creek and North Branch Chanarambie Creek.

5. *Little Rock River Complex (two stream segments in Minnesota), Nobles County, Minnesota.* The Little Rock River Complex is comprised of two stream segment in Minnesota and one stream segment in Iowa. Topeka shiners have recently been captured in portions of the Little Rock River watershed, both from streams and adjacent off-channel pools and oxbows. We propose the reaches of the Little Rock River from the Minnesota/Iowa border, upstream to near Rushmore, Minnesota, and portions of Little Rock Creek, including adjacent off-channel pool habitat.

6. *Mud Creek Complex (three stream segments), Rock County, Minnesota.* This complex is comprised of three stream segments. We propose portions of Mud Creek and two unnamed tributaries, and adjacent off-channel pool habitat for designation.

Nebraska

1. *Taylor Creek (one stream segment), Elkhorn River Watershed, Madison County, Nebraska.* A small population of Topeka shiners exists in this stream, with two recent captures of the species. This is the only stream in Nebraska with capture records for the species since 1989, and is the only proposed critical habitat in the greater Platte River watershed. Taylor Creek is somewhat modified in portions of its watershed, but retains several of the primary constituent elements necessary for designation as critical habitat, including stream morphology, pools, and instream habitat. The proposed reach of Taylor Creek is upstream from its confluence with Union Creek, near Madison, Nebraska.

South Dakota

Big Sioux River Watershed

1. *Hidewood Creek (one stream segment), Deuel and Hamlin Counties, South Dakota.* We propose to designate critical habitat on Hidewood Creek from its confluence with the Big Sioux River, to upstream of State Highway 15, including adjacent off-channel pool habitat.

2. *Peg Munky Run (one stream segment), Deuel County, South Dakota.* We propose habitat from State Highway 28, upstream to near Interstate Highway 29, including adjacent off-channel pool habitat. The downstream reach of this stream, to the confluence with the Big Sioux River, provides a possible corridor for dispersal by the species. However, this reach is highly channelized and does not have the necessary primary constituent elements present for proposing designation.

3. *Sixmile Creek Complex (two stream segments), Brookings County, South Dakota.* Habitat is proposed from near the confluence with the Big Sioux River, to upstream of White, South Dakota. The proposed reaches include portions of Sixmile Creek and an unnamed tributary, including adjacent off-channel pool habitat.

4. *Medary Creek Complex (three stream segments), Brookings County, South Dakota.* This complex is comprised of three stream segments in South Dakota and two in Minnesota. Topeka shiners have recently been captured from several localities in this complex. We propose for designation—Medary Creek from the confluence with the Big Sioux River, upstream to the South Dakota/Minnesota border; and portions of Deer Creek and an unnamed tributary, and adjacent off-channel pool habitat.

Lower Big Sioux Watershed

5. *Spring Creek (one stream segment), Brookings and Moody Counties, South Dakota.* The proposed reach runs from the confluence with the Big Sioux River, upstream to the South Dakota/Minnesota border, including adjacent off-channel pool habitat.

6. *Flandreau Creek Complex (one stream segment in South Dakota), Moody County, South Dakota.* This complex is comprised of one stream segment in South Dakota and four stream segments in Minnesota. Topeka shiners have been recently captured from several localities in this complex in Minnesota. No known collections exist from the reach proposed in South Dakota. However, this reach of stream is a likely dispersal corridor, and could be used as refugia for the species during long periods of drought. We propose for designation—Flandreau Creek, and adjacent off-channel pool habitat, from the confluence with the Big Sioux River, upstream to the South Dakota/Minnesota border.

7. *Brookfield Creek (one stream segment), Brookings County, South Dakota.* The stream reach proposed for designation runs upstream from the confluence with the Big Sioux River, including adjacent off-channel pool habitat.

8. *Slip-Up Creek (one stream segment), Minnehaha County, South Dakota.* The stream reach proposed for designation runs from the confluence with the Big Sioux River upstream, and includes adjacent off-channel pool habitat.

9. *Split Rock/Pipestone/Beaver Creek Complex (seven stream segments in South Dakota), Minnehaha and Moody Counties, South Dakota.* This complex is comprised of 7 stream segments in South Dakota and 18 in Minnesota. The streams and some of their adjacent off-channel pool habitats in this complex have recent collection records for Topeka shiner. While some habitat in these tributary streams has been altered, primarily by channelization and sedimentation, current habitat conditions provide most or all of the primary constituent elements consistent with designation as critical habitat. We propose for designation portions of—Split Rock Creek and an unnamed tributary; Pipestone Creek and an unnamed tributary; West Pipestone Creek; Beaver Creek; Fourmile Creek; and adjacent off-channel pool habitat within these reaches.

Vermillion River Watershed

10. *Vermillion River Complex (nine stream segments), Clay, Lincoln,*

McCook, Miner, and Turner Counties, South Dakota. This complex is comprised primarily of long reaches of the Vermillion River mainstem and West Fork Vermillion River. Additionally, several tributaries provide habitat for the species, with conditions varying across the complex. While some aquatic habitat has been altered, primarily by channelization and sedimentation, current habitat conditions provide most or all of the primary constituent elements consistent with designation as critical habitat. Topeka shiners have been captured in several locations within this complex, including the mainstem river reaches. It is likely that the species utilizes these mainstem reaches as dispersal corridors and refugia during periods of drought. We propose portions of the following streams for designation—Vermillion River; West Fork Vermillion River; East Fork Vermillion River; Silver Lake Creek; Camp Creek; Turkey Ridge Creek; Long Creek; Saddle Creek; and Blind Creek.

Lower James River Watershed

11. Lonetree Creek Complex (two stream segments), Hutchinson County, South Dakota. This complex provides the primary constituent elements necessary for designation as critical habitat, including natural stream morphology and instream habitat. We propose portions of Lonetree Creek immediately upstream from its confluence with the James River, and South Branch Lonetree Creek.

12. Dry Creek Complex (two stream segments), Hutchinson County, South Dakota. This complex provides the primary constituent elements necessary for designation as critical habitat, including natural stream morphology and instream habitat. We propose portions of Dry Creek upstream from its confluence with the James River and North Branch Dry Creek.

13. Wolf Creek (one stream segment), Hutchinson County, South Dakota. This stream is characterized by moderate quality aquatic habitat draining a mostly grassy floodplain and primarily cultivated uplands. The stream reach proposed for designation runs upstream from the confluence with the James River.

14. Twelve-mile Creek (one stream segment), Davison, Hanson, and Hutchinson Counties, South Dakota. This stream is characterized by moderate quality aquatic habitat draining a mostly grassy floodplain and primarily cultivated uplands. The stream reach proposed for designation upstream runs from the confluence with the James River.

15. Enemy Creek (one stream segment), Davison and Hanson Counties, South Dakota. This stream is characterized by moderate quality aquatic habitat draining a mostly grassy floodplain and primarily cultivated uplands. The stream reach proposed for designation runs upstream from the confluence with the James River.

16. Rock Creek (one stream segment), Davison, Hanson, and Miner Counties, South Dakota. This stream is characterized by moderate quality aquatic habitat draining a grassy floodplain and primarily cultivated uplands. The stream reach proposed for designation runs upstream from the confluence with the James River.

17. Firesteel Creek Complex (two stream segments), Aurora and Davison Counties, South Dakota. This complex provides the primary constituent elements necessary for designation as critical habitat, including natural stream morphology and instream habitat. We are proposing the reach of Firesteel Creek from near the headwaters of Lake Mitchell upstream to the confluence with West Branch Firesteel Creek and West Branch Firesteel upstream to near Wilmarth Lake.

Upper James River Watershed

18. Pearl Creek Complex (two stream segments), Beadle County, South Dakota. The streams in this complex are characterized by quality aquatic habitat draining a grassy floodplain and primarily cultivated uplands. Riparian conditions are good and appear stable. Recent records of Topeka shiners within these stream segments suggest a healthy and stable population. We propose for designation portions of Pearl Creek from its confluence with the James River upstream past its confluence with Middle Pearl Creek and a reach of Middle Pearl Creek upstream from its confluence with Pearl Creek.

19. Shue Creek (one stream segment), Beadle County, South Dakota. This stream is characterized by quality aquatic habitat draining a grassy floodplain and primarily cultivated uplands. The stream reach proposed for designation runs from Shue Creek's confluence with the James River upstream to Staum Dam.

Exclusions From Critical Habitat

Section 3(5) of the Act defines critical habitat, in part, as areas within the geographical area occupied by the species "on which are found those physical and biological features (I) essential to the conservation of the species and (II) which may require special management considerations and protection." Special management

consideration is not required if adequate management or protection is already in place. Adequate special management consideration or protection is provided by a legally operative plan or agreement that addresses the maintenance and improvement of the primary constituent elements important to the species and manages for the long-term conservation of the species. We use the following three criteria to determine if a plan provides adequate special management or protection—(1) A current plan or agreement must be complete and provide sufficient conservation benefit to the species; (2) the plan must provide assurances that the conservation management strategies will be implemented; and (3) the plan must provide assurances that the conservation management strategies will be effective, (*i.e.*, provide for periodic monitoring and revisions as necessary). If all of these criteria are met, then lands covered under the plan would no longer meet the definition of critical habitat.

Missouri—Exclusion Under Section 3(5)(A)

In Missouri, the Topeka shiner historically occurred in small, headwater streams in northern portions of the State, within the Missouri/Grand River Watershed. This area has been designated as Primary Recovery Unit 5 by the Topeka Shiner Recovery Team in the preliminary Draft Topeka Shiner Recovery Plan. The Topeka shiner has been a focal species for planning and conservation efforts on various levels in the State since the mid-1990s. In 1995, the Missouri Department of Conservation (MDC) established a 5-member Topeka shiner Working Group and a 16-member Advisory Group to direct, implement, and facilitate Topeka shiner recovery actions in Missouri. In 1996, MDC, with approval of the Conservation Commission of Missouri (Conservation Commission), listed the Topeka shiner as an endangered species under the State's Wildlife Code (Conservation Commission of Missouri 2001). In January 1999, MDC adopted and approved an Action Plan for the Topeka shiner (*Notropis topeka*) in Missouri (Action Plan) (Missouri Department of Conservation 1999). The Action Plan identifies comprehensive conservation measures and programs necessary to achieve recovery of the Topeka shiner in Missouri. Implementation of recovery efforts for the Topeka shiner in Missouri as outlined in this plan are ongoing. In 1999, the Conservation Commission established the Private Lands Services Division within MDC. Eighty-three MDC staff were redirected to private land

conservation throughout the State, including a minimum of 16 Private Lands Services personnel with responsibility for the counties in Primary Recovery Unit 5. Duties of personnel within this division include the facilitation of conservation efforts on private property throughout Missouri for all federally listed species, including the Topeka shiner. Additionally, there are at least 86 fisheries, forestry, natural history, protection, and wildlife staff delivering services to private landowners as a routine aspect of their job within Primary Recovery Unit 5.

Within the Missouri/Grand Watershed in Missouri, the following Topeka shiner conservation actions have been completed or are ongoing—(1) Establishment of the Missouri Topeka Shiner Working Group to direct the recovery of the species throughout the State; (2) the development and ongoing implementation of the Action Plan; (3) establishment of permanent sampling sites and standardized monitoring of Missouri's Topeka shiner populations and completion of a recent state-wide survey for the species (Gelwicks and Bruenderman 1996); (4) initiation of artificial propagation of Topeka shiners including the development and refinement of captive rearing techniques that will be applicable across the range of the species; (5) completion of genetic analyses of different populations of Topeka shiners in Missouri; (6) incorporation of Topeka shiner recovery and conservation efforts in State strategic planning documents on several different levels (*e.g.*, regional management guidelines, watershed inventory and assessment plans, hatchery plans, conservation area plans, various division work plans) that facilitate the implementation of activities identified in the State Action Plan and the Service's preliminary draft Recovery Plan; (7) development and dissemination of public outreach and education materials throughout Missouri and elsewhere within the range of the species (*e.g.*, Best Management Plans, posters, pamphlets, "critter" collector cards; various articles published in the Missouri Conservationist magazine); (8) completion and dissemination of several ecological and life history studies involving Topeka shiner; (9) securing matching funds from the Service (*e.g.*, Cooperative Endangered Species Conservation Fund, Partners for Fish and Wildlife) to conduct surveys and ecological studies, and for various habitat restoration and enhancement activities; and (10) revision of the Action Plan that will include actions

not yet completed since 1999 and those uncompleted actions identified in the Service's preliminary draft Recovery Plan. Revision of the Action Plan will include a detailed implementation schedule following the Service's timetable outlined in the Service's preliminary draft Recovery Plan.

Other specific Topeka shiner conservation efforts being undertaken within the Missouri/Grand Watershed in Missouri in accordance with the Action Plan are—(1) Implementation of a landowner incentive program and completion of a study on the potential impacts of Confined Animal Feeding Operations within the Moniteau Creek Watershed; (2) development of 10-year fish monitoring plans for the Moniteau, Bon Femme, and Sugar Creek watersheds; (3) development and implementation of a Sugar Creek sub-basin management plan; (4) development and implementation of a Three Creeks Conservation Area Management Plan within the Bon Femme Creek Watershed; (5) protection and management of Bon Femme Creek by establishing these watersheds as Missouri Department of Natural Resources' Agricultural Non-point Source Pollution Special Area Land Treatment watersheds; and (6) reestablishment or restoration of riparian corridors through tree plantings, natural regeneration, fencing to restrict livestock use of stream banks, creation of alternative livestock watering sources, establishment of warm season grass buffer strips, streambank stabilization activities, and actions outlined in a grazing plan developed for private landowners within the Bon Femme, Moniteau, and Sugar Creek watersheds. Additionally, 10 Missouri Stream Teams formally "adopted" various stretches of occupied Topeka shiner habitat within the Bon Femme, Moniteau, and Sugar Creek watersheds. Stream teams assist in the conservation of the Topeka shiner in these watersheds by promoting local citizen awareness of Topeka shiners and stream health, and by direct involvement with stream cleaning and water quality monitoring activities.

Additional assurances that the Action Plan will be implemented and conservation of the Topeka shiner will be achieved in Missouri is demonstrated by the following actions—(1) To date, at least \$105,000 has been expended on recovery actions for the Topeka shiner in Missouri, and is likely to increase to at least \$600,000 within the next 10 years; (2) 80 percent (*i.e.*, 12 of 15) of the priority 1 tasks (*i.e.*, those actions deemed necessary to prevent extinction of the species) identified and outlined

in the implementation schedule of the Service's preliminary draft Recovery Plan have either been completed or are currently being implemented by MDC in cooperation with us, the Topeka Shiner Recovery Team, and other Federal, State, and private entities; (3) the Private Land Services Division within MDC greatly facilitates the implementation of recovery actions on private property where the species currently exists or where the species may be reintroduced; (4) planned expansion of our Partners for Fish and Wildlife Program within Topeka shiner-occupied habitat to benefit an additional 10–15 landowners at an estimated cost of \$100,000 within the next 5 years (Kelly Srigley Werner, Fish and Wildlife Service Missouri Private Lands Coordinator, pers. comm.); (5) commitments by MDC Fisheries and Natural History divisions staff to help coordinate and implement Topeka shiner recovery efforts between MDC and Federal, State, and private entities, and MDC's Topeka Shiner Recovery Coordinator; (6) active participation by MDC on the Topeka Shiner Recovery Team; and (7) revisions to the Action Plan, scheduled for completion within the current calendar year, will focus on incorporating any of the recovery actions outlined in the Service's preliminary draft Recovery Plan that are currently not addressed. The scientific soundness of MDC's Action Plan was further validated by us and the Recovery Team when the Action Plan's monitoring protocol and recommendations for reducing and eliminating threats to the Topeka shiner were incorporated, in part, into the Service's preliminary draft Recovery Plan.

We evaluated the Action Plan and associated Topeka shiner conservation actions that have been completed, ongoing, or planned in Missouri against our three criteria used to determine whether lands require "special management considerations or protections," under the definition of critical habitat in section 3 of the Act. The Action Plan clearly provides conservation benefits to the species; the Action Plan provides assurances that conservation efforts will be implemented since MDC has authority to implement the plan, has put in place the funding and staffing necessary to implement the Plan, and has completed or begun work on many significant elements of the Plan; and the Action Plan and efforts of MDC will be effective since they include biological goals, restoration objectives, and monitoring consistent with the preliminary draft

Recovery Plan. Therefore, we determined that all Topeka shiner areas in Missouri (Primary Recovery Unit 5) do not meet the definition of critical habitat because there is adequate special management or protection, and we did not include them in this proposal.

Fort Riley, Kansas (Department of the Army)—Exclusion Under Section 3(5)(A)

The Fort Riley Military Installation, located in Riley and Geary Counties, Kansas, is primarily an infantry and tank training facility. Fort Riley lies within the Flint Hills Region of Kansas and has several low order streams that drain to the Kansas River. Presently, the Topeka shiner occurs in four streams on Fort Riley—Wildcat Creek and its tributaries, Wind Creek, Little Arkansas Creek, and Sevenmile Creek. These streams are within Primary Recovery Unit 1, as designated by the preliminary draft Topeka Shiner Recovery Plan.

The Topeka shiner has been a focal species for planning and conservation efforts on Fort Riley since the early 1990s, with numerous stream surveys occurring from this time to the present. Development of management guidelines for the species was initialized in 1994. The first Endangered Species Management Plan for Topeka Shiner on Fort Riley was formalized in 1997. This management plan was revised and incorporated into Fort Riley's Integrated Natural Resource Management Plan 2001–2005, which was formalized July 30, 2001 (Keating, Ft. Riley Natural Resources Division, pers. comm. 2002). This management plan outlines and describes—conservation goals; management prescriptions and actions; a monitoring plan; estimates of time, cost, and personnel needed; a checklist of tasks; and an annual report (Department of the Army 2001).

We evaluated the Fort Riley Endangered Species Management Plan for Topeka Shiner and the Fort's associated Topeka shiner conservation actions that have been completed, ongoing, or planned, against our three criteria used to determine whether lands require "special management considerations or protections," under the definition of critical habitat in section 3 of the Act. This management plan provides conservation benefits to the species; the plan provides assurances that conservation efforts will be implemented; and the plan and efforts of the Army will be effective since they include biological goals, restoration objectives, and monitoring consistent with the draft Recovery Plan. Therefore, we determine that all Topeka shiner areas on Fort Riley do not meet

the definition of critical habitat because there is adequate special management or protection, and we did not include them in this proposal.

Land Ownership

The vast majority (approximately 98 percent) of proposed critical habitat is in private ownership. Private lands are primarily used for grazing and agriculture, but also include some urban, suburban, and industrial areas. Additionally, there are small, scattered tracts of State and Federal lands.

Effects of Critical Habitat Designation

Designating critical habitat does not, in itself, lead to the recovery of a listed species. The designation does not establish a reserve, create a management plan, establish numerical population goals, prescribe specific management practices (inside or outside of critical habitat), or directly affect areas not designated as critical habitat. Specific management recommendations for areas designated as critical habitat are most appropriately addressed in recovery and conservation plans, and through section 7 consultation and section 10 permits.

However, designation of critical habitat can help focus conservation activities for listed species by identifying areas essential to conserve the species. Designation of critical habitat also alerts the public, as well as land-managing agencies, to the importance of these areas. As a result of critical habitat designation, Federal agencies may be able to prioritize landowner incentive programs such as Conservation Reserve Program enrollment and other private landowner agreements that benefit the Topeka shiner. Critical habitat designation also may assist States and local governments in prioritizing their conservation and land management programs.

Section 7 Consultation

The regulatory effects of a critical habitat designation under the Act are triggered through the provisions of section 7, which apply only to activities conducted, authorized, or funded by a Federal agency (Federal actions). Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR 402. Individuals, organizations, States, local governments, and other non-Federal entities are not affected by the designation of critical habitat unless their actions occur on Federal lands, require Federal authorization, or involve Federal funding.

Section 7(a)(2) of the Act requires Federal agencies, including us, to insure that their actions are not likely to

jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. This requirement is met through section 7 consultation under the Act. Adverse modification might result from alterations that include, but are not limited to, adverse changes to the physical or biological features, *i.e.*, the primary constituent elements that were the basis for determining the habitat to be critical.

Conference for Proposed Critical Habitat

Section 7(a)(4) of the Act requires Federal agencies to confer with us on any action that is likely to result in the destruction or adverse modification of proposed critical habitat. The regulations for interagency cooperation regarding proposed critical habitat are codified at 50 CFR 402.10. During a conference on the effects of a Federal action on proposed critical habitat, we make nonbinding recommendations on ways to minimize or avoid adverse effects of the action. We document these recommendations and any conclusions reached in a conference report provided to the Federal agency and to any applicant involved.

If requested by the Federal agency and deemed appropriate by us, the conference may be conducted in accordance with the procedures for formal consultation under 50 CFR 402.14. We may adopt an opinion issued at the conclusion of the conference as our biological opinion when the critical habitat is designated by final rule, but only if new information or changes to the proposed Federal action would not significantly alter the content of the opinion.

Consultation for Designated Critical Habitat

If a Federal action may affect a listed species or its designated critical habitat, the action agency must initiate consultation with us (50 CFR 402.14). Through this consultation, we would advise the agency whether the action would likely jeopardize the continued existence of the species or adversely modify its critical habitat.

When we issue a biological opinion that concludes that an action is likely to result in the destruction or adverse modification of critical habitat, we must provide reasonable and prudent alternatives to the action, if any are identifiable. Reasonable and prudent alternatives are actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the proposed action, are

consistent with the scope of the action agency's authority and jurisdiction, are economically and technologically feasible, and would likely avoid the destruction or adverse modification of critical habitat (50 CFR 402.02).

Reinitiation of Prior Consultations

A Federal agency may request a conference with us for any previously reviewed action that is likely to destroy or adversely modify proposed critical habitat and over which the agency retains discretionary involvement or control, as described above under "Conference for Proposed Critical Habitat." Following designation of critical habitat, regulations at 50 CFR 402.16 require a Federal agency to reinitiate consultation for previously reviewed actions that may affect critical habitat and over which the agency has retained discretionary involvement or control.

Federal Actions That May Destroy or Adversely Modify Topeka Shiner Critical Habitat

Section 4(b)(8) of the Act requires us to include in any proposed or final regulation that designates critical habitat a description and evaluation of those activities involving a Federal action that may adversely modify such habitat or that may be affected by such designation. A wide range of Federal activities have the potential to destroy or adversely modify critical habitat for the Topeka shiner. These activities may include land and water management actions of Federal agencies (e.g., U.S. Army Corps of Engineers, Natural Resources Conservation Service, and Bureau of Reclamation), and related or similar actions of other federally regulated projects (e.g., road and bridge construction activities by the Federal Highway Administration; dredge and fill projects, sand and gravel mining, and bank stabilization activities conducted or authorized by the U.S. Army Corps of Engineers; and National Pollutant Discharge Elimination System permits authorized by the Environmental Protection Agency). Specifically, activities that may destroy or adversely modify critical habitat are those that alter the primary constituent elements (defined above) to an extent that the value of critical habitat for both the survival and recovery of the Topeka shiner is appreciably reduced. Such activities include, but are not limited to:

(1) Significantly and detrimentally altering the minimum flow or the natural flow regime of any of the designated stream segments. Possible actions include groundwater pumping, impoundment, and water diversion. We

note that flow reductions that result from actions affecting tributaries of the proposed stream reaches also may destroy or adversely modify critical habitat;

(2) Significantly and detrimentally altering the characteristics of the riparian zone in any of the designated stream segments. Possible actions would include vegetation manipulation, timber harvest, road construction and maintenance, livestock grazing, off-road vehicle use, powerline or pipeline construction and repair, mining, and urban and suburban development;

(3) Significantly and detrimentally altering the channel morphology of any of the stream segments listed above. Possible actions include channelization, impoundment, road and bridge construction, deprivation of substrate source, destruction and alteration of riparian vegetation, reduction of available floodplain, removal of gravel or floodplain terrace materials, reduction in stream flow, and excessive sedimentation from mining, livestock grazing, road construction, timber harvest, off-road vehicle use, and other watershed and floodplain disturbances;

(4) Significantly and detrimentally altering the water chemistry in any of the designated stream segments. Possible actions include release of chemical or biological pollutants into the surface water or connected groundwater at a point source or by dispersed release (non-point); and

(5) Introducing, spreading, or augmenting nonnative aquatic species in any of the designated stream segments. Possible actions include fish stocking for sport, aesthetics, biological control, or other purposes; use of live bait fish; aquaculture; construction and operation of canals; and interbasin water transfers.

Not all of the identified activities are necessarily of current concern within the range of the Topeka shiner; however, they do indicate the potential types of activities that will require consultation in the future and, therefore, may be affected by critical habitat designation. We note that the areas we propose for designation as critical habitat for the Topeka shiner are occupied by the species, and actions that adversely modify critical habitat may also jeopardize the continued existence of the species.

As discussed previously, Federal actions that are found likely to destroy or adversely modify critical habitat may often be modified, through development of reasonable and prudent alternatives, in ways that will remove the likelihood of destruction or adverse modification of critical habitat. Such project

modifications may include such things as adjusting the timing of projects to avoid sensitive periods for the species and its habitat; replanting riparian vegetation; minimizing work and vehicle use in the wetted channel; restricting riparian and upland vegetation clearing; fencing to exclude livestock and limit recreational use; use of alternative livestock management techniques; avoidance of pollution; minimizing ground disturbance in the floodplain; use of alternative material sources; storage of equipment and staging of operations outside the floodplain; use of sediment barriers; access restrictions; and use of best management practices to minimize erosion.

If you have questions regarding whether specific activities will likely constitute destruction or adverse modification of critical habitat, contact the Field Supervisor, Kansas Ecological Services Field Office (*see ADDRESSES* section). Requests for copies of the regulations on listed wildlife and inquiries about prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Division of Endangered Species, P.O. Box 25486, Denver Federal Center, Denver, Colorado 80225 (telephone 303-236-7400; facsimile 303-236-0027).

A preliminary draft recovery plan for the Topeka shiner has been developed and is undergoing internal review prior to being formally proposed, peer-reviewed by scientists, and published to solicit public comments. The recovery plan, when finalized, will provide recommendations on recovering this species, including recommendations on management of critical habitat. Should the recovery plan recommend adding or deleting areas as critical habitat, we will consider whether a future revision of critical habitat is appropriate.

Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial information available, and to consider the economic and other relevant impacts of designating these areas as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of designating these areas as critical habitat. We cannot exclude areas from critical habitat when the exclusion will result in the extinction of the species. We will conduct an analysis of the economic impacts of designating these areas as critical habitat prior to a final determination. When completed, we will announce the availability of the

draft economic analysis with a notice in the **Federal Register**, and, if necessary, reopen the comment period at the time to accept comments on the economic analysis or further comments on the proposed rule. The economic analysis will be available at <http://mountain-prairie.fws.gov/topekashiner/ch>. This economic analysis will serve as the basis of our analysis under section 4(b)(2), and of any exclusions. As this economic analysis is not yet completed, we are not yet able to identify proposed exclusions under section 4(b)(2) in this proposed rule. We will review this analysis, public comments on the analysis and this proposed rule, and the benefits of designating areas as critical habitat; we may identify certain proposed areas that should be excluded from the final critical habitat designation, provided these exclusions will not result in the extinction of the species. As a result, the final critical habitat determination may differ from this proposal.

American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act

In accordance with the Presidential Memorandum of April 29, 1994, we believe that, to the maximum extent possible, tribes should be the governmental entities to manage their lands and tribal trust resources. To this end, we support tribal measures that preclude the need for conservation regulations, and we provide technical assistance to Indian tribes who wish assistance in developing and expanding tribal programs for the management of healthy ecosystems so that Federal conservation regulations, such as designation of critical habitat, on tribal lands are unnecessary. The Presidential Memorandum of April 29, 1994, also requires us to consult with the tribes on matters that affect them, and section 4(b)(2) of the Act requires us to gather information regarding the designation of critical habitat and the effects thereof from all relevant sources, including the tribes.

In examining the geographic extent of areas proposed for designation as critical habitat, we did not identify any tribal trust resources, tribally owned fee lands, or tribal rights that might be affected by the designation. Our South Dakota Field Office corresponded with the Bureau of Indian Affairs (BIA), Great Plains Regional Office, which identified two potentially affected tribes, the Sisseton—Wahpeton Sioux Tribe and the Flandreau Santee Sioux Tribe. The BIA communicated that these tribes do have land held in trust, either by the tribe or individuals, within the general

range of the Topeka shiner, but did not provide locality information. We further contacted the tribes. The Sisseton—Wahpeton Sioux Tribe responded with general information on potential Topeka shiner habitat on their tribal lands and requested funding from the Service and the BIA for surveys for the Topeka shiner. However, up to the time of this publication, no maps identifying the location of these trust lands have been provided. Therefore, we are unable to identify any tribal trust lands potentially proposed for designation as critical habitat. We do not anticipate that proposal of critical habitat on non-tribal lands will result in any impact on tribal trust resources or the exercise of tribal rights. In complying with our tribal trust responsibilities, we must communicate with all tribes potentially affected by the designation. Therefore, we are soliciting additional information during the comment period on potential effects to the tribes or tribal resources that may result from critical habitat designation.

Public Comments Solicited

We intend for any final action resulting from this proposal to be as accurate and effective as possible. Therefore, we are soliciting comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party regarding this proposed rule. We particularly seek comments concerning:

(1) The reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefits of excluding areas will outweigh the benefits of including areas as critical habitat;

(2) Specific information on the abundance of the Topeka shiner and the amount and distribution of its habitat;

(3) Areas that are essential to the conservation of the species and that may require special management considerations or protection and why;

(4) Land use practices and current or planned activities in the subject areas and their possible impacts on proposed critical habitat;

(5) Any foreseeable economic or other impacts resulting from the proposed designation of critical habitat, in particular, any impacts on small entities or families; and

(6) Economic and other values associated with designating critical habitat for the Topeka shiner, such as those derived from nonconsumptive uses (e.g., hiking, camping, birding, enhanced watershed protection, increased soil retention, existence

values, and reductions in administrative costs).

Our practice is to make comments that we receive on this rulemaking, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish for us to withhold your name and/or address, you must state this request prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, including the individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Clarity of the Rule

Executive Order 12866 requires each agency to write regulations and notices that are easy to understand. We invite your comments on how to make this proposed rule easier to understand including answers to questions such as the following:

(1) Are the requirements in the document clearly stated?

(2) Does the proposed rule contain technical language or jargon that interferes with the clarity?

(3) Does the format of the proposed rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity?

(4) Is the description of the proposed rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the document?

(5) What else could we do to make the proposed rule easier to understand?

Send a copy of any comments that concern how we could make this proposed rule easier to understand to—Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240. You also may e-mail comments to Exsec@ios.doi.gov.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of such review is to ensure listing decisions are based on scientifically sound data, assumptions, and analyses. We will

send copies of this proposed rule immediately following publication in the **Federal Register** to these peer reviewers. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed designation of critical habitat. We will consider all comments and information received during the comment period on this proposed rule during preparation of a final rulemaking. Accordingly, the final decision may differ from this proposal.

Public Hearings and Meetings

The Act provides for one or more public hearings or meetings on this proposal, if requested. Given the large geographic extent covered by this proposal, we have scheduled six public meetings.

Public meetings will be held at:

1. Manhattan, KS, on September 4, 2002, at the Ramada Inn, Landon Room, 17th and Anderson Avenue;
2. Bethany, MO, on September 5, 2002, at the Bethany Community Center, 105 North 25th Street;
3. Fort Dodge, IA, on September 9, 2002, at the Best Western Starlite Village, 1518 3rd Avenue NW.;
4. Pipestone, MN, on September 10, 2002, at the Pipestone National Monument;
5. Sioux Falls, SD, on September 11, 2002, at the Country Inn and Suites, Riverfront Room, 200 East 8th Street;
6. Madison, NE., on September 12, 2002, at the Shelter House, 300 West 10th Street.

All public meetings will run from 6 p.m. to 9 p.m.

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, this document is a significant rule and was reviewed by the Office of Management and Budget (OMB). The Service is preparing a draft economic analysis of this proposed rule, and will use this analysis to meet the requirement of section 4(b)(2) of the ESA to determine the economic consequences of designating the specific areas as critical habitat and excluding any area from critical habitat if it is determined that the benefits of exclusion outweigh the benefits of specifying such areas as part of the critical habitat, unless failure to designate such areas as critical habitat will lead to the extinction of the Topeka shiner. This analysis will be available for public comment before finalizing this designation. The availability of the draft economic analysis will be announced in the **Federal Register**.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

In the economic analysis, we will determine whether designation of critical habitat will have a significant effect on a substantial number of small entities. As discussed under Regulatory Planning and Review above, this rule is expected to result in few, if any, restrictions in addition to those currently in existence. As indicated on Table 1 (*see Critical Habitat Designation*), we designated property owned by Federal and State governments, and private entities.

Within these areas, the types of Federal actions or authorized activities that we have identified as potential concerns are:

- (1) Regulation of activities affecting waters of the United States by the Corps under section 404 of the Clean Water Act, and section 10 of the Rivers and Harbors Act;
- (2) Regulation of water flows, water delivery, and diversion by Federal agencies;
- (3) Sale, exchange, or lease of lands owned by a Federal agency;
- (4) Road construction and maintenance and right-of-way designation;
- (5) Funding of low-interest loans to facilitate the construction of low-income housing by the Department of Housing and Urban Development;
- (6) Hazard mitigation and post-disaster repairs funded by the Federal Emergency Management Agency;
- (7) Promulgation of air and water quality standards under the Clean Air Act and the Clean Water Act and the cleanup of toxic waste and superfund sites under the Resource Conservation and Recovery Act and the Comprehensive Environmental Response, Compensation, and Liability Act by the U.S. Environmental Protection Agency;
- (8) Issuance of Endangered Species Act section 10(a)(1)(B) permits by the Fish and Wildlife Service; and
- (9) Activities funded, carried out, or authorized by any Federal agency.

Many of these activities sponsored by Federal agencies within the proposed critical habitat areas are carried out by small entities (as defined by the Regulatory Flexibility Act) through contract, grant, permit, or other Federal authorization. As discussed above, these actions are currently required to comply with the listing protections of the Act, and the designation of critical habitat is not anticipated to have any additional effects on these activities in areas of critical habitat occupied by the species. In the economic analysis, we will

evaluate whether designation of critical habitat will have an effect on activities carried out by small entities.

For actions on non-Federal property that do not have a Federal connection (such as funding or authorization), the current restrictions concerning take of the species remain in effect, and this rule will have no additional restrictions.

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2))

In the economic analysis, we will determine whether designation of critical habitat will cause—(a) Any effect on the economy of \$100 million or more, (b) any increases in costs or prices for consumers, individual industries, Federal, State, Tribal, or local government agencies, or geographic regions, or (c) any significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

Executive Order 13211

On May 18, 2001, the President issued an Executive Order (Executive Order 13211) on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. As this proposed rule is not expected to significantly affect energy supplies, distribution, or use, this action is not a significant energy action and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) the Service will use the economic analysis to further evaluate this situation.

Takings

In accordance with Executive Order 12630, this rule does not have significant takings implications, and a takings implication assessment is not required. This determination will not “take” private property and will not alter the long-term value of private property. As discussed above, the designation of critical habitat affects only Federal agency actions. The rule will not increase or decrease the current restrictions on private property concerning take of Topeka shiner as defined in section 9 of the Act and its implementing regulations (50 FR 17.31). Due to current public knowledge of the species’ protection, the prohibition against take of Topeka shiner both within and outside of the proposed areas, and the fact that critical habitat

provides no incremental restrictions, we do not anticipate that property values will be affected by the critical habitat designation. While real estate market values may temporarily decline following designation, due to the perception that critical habitat designation may impose additional regulatory burdens on land use, we expect any such impacts to be short term. Additionally, critical habitat designation does not preclude development of habitat conservation plans and issuance of incidental take permits. Landowners in areas that are included in the designated critical habitat will continue to utilize their property in ways consistent with the conservation of the Topeka shiner.

Federalism

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior policy, the Service requested information from and coordinated development of this critical habitat proposal with appropriate State resource agencies in Iowa, Kansas, Minnesota, Missouri, Nebraska, and South Dakota, as well as during the listing process. We will continue to coordinate any future designation of critical habitat for Topeka shiner with the appropriate State agencies. The designation of critical habitat for the Topeka shiner imposes few additional restrictions to those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments in that the areas essential to the conservation of the species are more clearly defined and the primary constituent elements of the habitat necessary to the conservation of the species are specifically identified. While making this definition and identification does not alter where and what federally sponsored activities may occur, doing so may assist these local governments in long-range planning (rather than waiting for case-by-case section 7 consultations to occur).

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has

determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are proposing to designate critical habitat in accordance with the provisions of the Act and plan public meetings on the proposed designation during the comment period. The rule uses standard property descriptions and identifies the primary constituent elements within the designated areas to assist the public in understanding the habitat needs of the Topeka shiner.

Paperwork Reduction Act of 1995

This rule does not contain any information collection requirements for which OMB approval under the Paperwork Reduction Act is required. Information collections associated with Endangered Species permits are covered by an existing OMB approval and are assigned control number 1018-0094, which expires on July 31, 2004. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

National Environmental Policy Act

Our position is that, outside the Tenth Circuit, we do not need to prepare environmental analyses as defined by the National Environmental Policy Act (NEPA) in connection with designating critical habitat under the Endangered Species Act of 1973, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld in the courts of the Ninth Circuit (*Douglas County v. Babbitt*, 48 F.3d 1495 (Ninth Cir. Ore. 1995), cert. denied 116 S. Ct. 698 (1996)). However, when the range of the species includes States within the 10th Circuit, pursuant to the 10th Circuit ruling in *Catron County Board of Commissioners v. U.S. Fish and Wildlife Service*, 75 F.3d 1429 (10th Cir. 1996), we will complete a NEPA analysis with an Environmental Assessment. The range of the Topeka shiner includes States within the 10th Circuit; therefore, we are completing an Environmental Assessment and will announce its availability in the **Federal Register**.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, *"Government-to-Government Relations with Native American Tribal Governments"* (59 FR 22951), Executive Order 13175, and 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. We are required to assess the effects of critical habitat designation on tribal lands and tribal trust resources. We believe that no tribal lands or tribal trust resources are essential for the conservation of the Topeka shiner.

References Cited

A complete list of all references cited in this proposed rule is available upon request from the Kansas Ecological Services Field Office (*see* **ADDRESSES**).

Author

The primary author of this proposed rule is Vernon Tabor, Kansas Ecological Services Field Office (*see* **ADDRESSES**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species,
Exports, Imports, Reporting and
recordkeeping requirements,
Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.11(h), by revising the entry for “Shiner, Topeka” under “FISHES” to read as follows:

§ 17.11 Endangered and threatened wildlife.

$$\begin{array}{ccccc} * & & * & & * & & * & & * \\ \text{(h)} & * & & * & & * & & & \end{array}$$

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
FISHES							

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
* Shiner, Topeka	* (<i>Notropis topeka=tristis</i>).	* U.S.A. (IA, KS, MN, MO, NE, SD).	* Entire	* E	* 654	* 17.95(e)	* N/A
*	*	*	*	*	*	*	*

3. Amend § 17.95(e) by adding critical habitat for the Topeka shiner (*Notropis topeka*) in the same alphabetical order as this species occurs in § 17.11(h).

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(e) *Fishes.* * * *

Topeka Shiner (*Notropis topeka*)

(1) Critical habitat is depicted for Calhoun, Carroll, Dallas, Greene, Hamilton, Lyon, Osceola, Sac, Webster, and Wright Counties, Iowa; Butler, Chase, Dickinson, Geary, Greenwood, Marion, Marshall, Morris, Pottawatomie, Riley, Shawnee, Wabaunsee, and Wallace Counties, Kansas; Lincoln, Murray, Nobles, Pipestone, and Rock Counties, Minnesota; Madison County, Nebraska; Aurora, Beadle, Brookings, Clay, Davison, Deuel, Hamlin, Hanson, Hutchinson, Lincoln, McCook, Miner, Minnehaha, Moody, and Turner Counties, South Dakota, on the maps and as described below.

(2) Critical habitat includes all proposed stream channels up to the bankfull discharge elevation. Additionally, in Iowa, Minnesota, and the Big Sioux River drainage of South Dakota, the off-channel, side-channel, and oxbow pools at elevations at or below the bankfull discharge elevation. Bankfull discharge is the flow at which water begins to leave the channel and move into the floodplain and generally occurs with a frequency of every 1 to 2 years.

(3) Within these areas, the primary constituent elements include, but are not limited to, those habitat components that are essential for the primary biological needs of foraging, sheltering, and reproduction. These elements include the following for Topeka shiner—(1) Streams most often with permanent flow, but that can become intermittent during dry periods; (2) Side channel pools and oxbows either seasonally connected to a stream or maintained by groundwater inputs, at a surface elevation equal to or lower than the bankfull discharge stream elevation. The bankfull discharge is the flow at which water begins leaving the channel and flowing into the floodplain; this level is generally attained every 1 to 2 years. Bankfull discharge, while a function of the size of the stream, is a fairly constant feature related to the formation, maintenance, and dimensions of the stream channel; (3) Streams and side channel pools with water quality necessary for unimpaired behavior, growth, and viability of all life stages. (The water quality components include—temperature, turbidity, conductivity, salinity, dissolved oxygen, pH, chemical contaminants, and other chemical characteristics); (4) Living and spawning areas for adult Topeka shiner with pools or runs with water velocities less than 0.5 meters/second (approx. 20 inches/second) and depths ranging from 0.1–2.0 meters (approx. 4–80 inches); (5) Living areas for juvenile Topeka shiner with water velocities less than 0.5 meters/second (approx. 20 inches/second) with depths less than 0.25

meters (approx. 10 inches) and moderate amounts of instream aquatic cover, such as woody debris, overhanging terrestrial vegetation, and aquatic plants; (6) Sand, gravel, cobble, and silt substrates with amounts of fine sediment and substrate embeddedness that allows for nest building and maintenance of nests and eggs by native *Lepomis* sunfishes (green sunfish, orangespotted sunfish, longear sunfish) and Topeka shiner as necessary for reproduction, unimpaired behavior, growth, and viability of all life stages; (7) An adequate terrestrial, semiaquatic, and aquatic invertebrate food base that allows for unimpaired growth, reproduction, and survival of all life stages; (8) A hydrologic regime capable of forming, maintaining, or restoring the flow periodicity, channel morphology, fish community composition, off-channel habitats, and habitat components described in the other primary constituent elements; and (9) Few or no nonnative predatory or competitive nonnative species present.

(4) Critical habitat was identified using—the Fifth Principal Meridian in Iowa, Missouri, and Minnesota; the Sixth Principal Meridian in Kansas and Nebraska; U.S. Geological Survey 30*60 minute (1:100,000) quadrangle maps; the National Hydrography Dataset (1:100,000) for hydrology; and Digital Line Graph (1:2,000,000) for county and State boundaries.

(5) Map 1 follows:

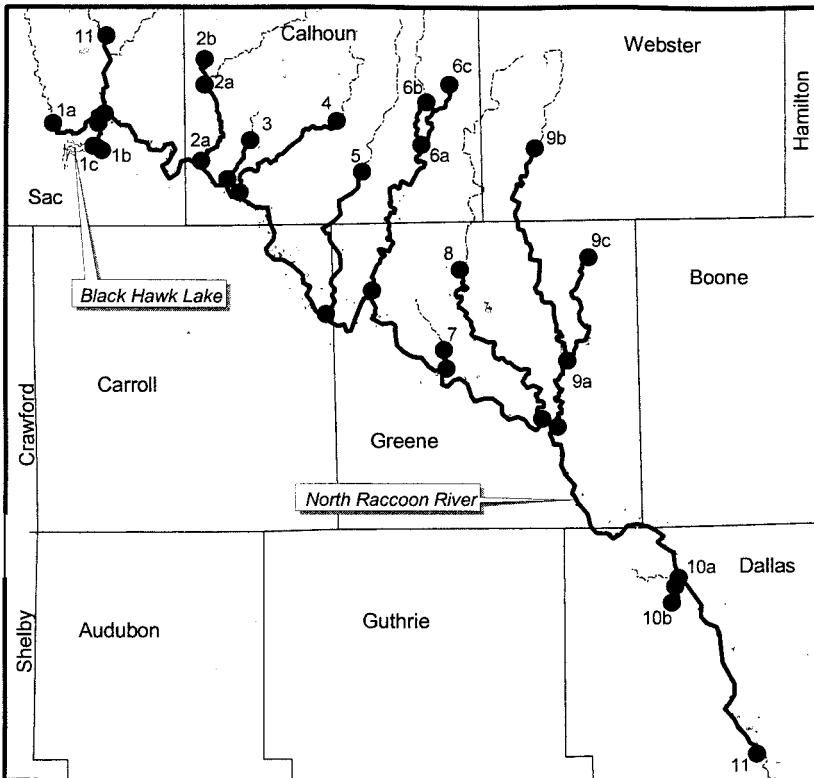
BILLING CODE 4310–55–P

Map 1

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

Iowa - North Raccoon River Watershed



Reaches

- 1a. Indian Creek
- 1b. Ditch 57
- 1c. Outlet Creek
- 2. Camp Creek
- 3. Prairie Creek
- 4. Lake Creek
- 5. Purgatory Creek
- 6a. Cedar Creek
- 6b. West Cedar Creek
- 6c. East Cedar Creek
- 7. Short Creek
- 8. Hardin Creek
- 9a. Buttrick Creek
- 9b. West Buttrick Creek
- 9c. East Buttrick Creek
- 10a. Elm Branch
- 10b. Swan Lake Branch
- 11. Off-channel and side channel pools adjacent to North Raccoon River

5 0 5 10 15 20 Miles



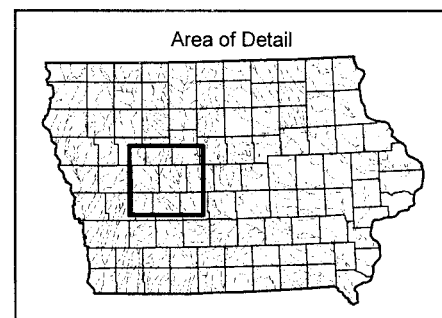
Proposed Critical Habitat



Not Proposed as Critical Habitat



County Lines



DISCLAIMER

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North Raccoon River Complex

1a. Indian Creek from its confluence with the North Raccoon River (T87N, R35W, Sec. 24), upstream through T87N, R35W, Sec. 29.

1b. Tributary to Indian Creek (Ditch 57), from their confluence (T87N, R35W, Sec. 23), upstream to the confluence with the outlet creek from Black Hawk Lake (T86N, R36W, Sec. 1).

1c. Outlet Creek from Black Hawk Lake from its confluence with Ditch 57 (T86N, R36W, Sec. 1), upstream to lake outlet (T87N, R35W, Sec. 35).

2a. Camp Creek from its confluence with the North Raccoon River (T86N, R34W, Sec. 7), upstream through T87N, R34W, Sec. 8.

2b. West Fork Camp Creek from its confluence with Camp Creek (T87N, R34W, Sec. 8), upstream through T88N, R34W, Sec. 32.

3. Prairie Creek from its confluence with the North Raccoon River (T86N, R34W, Sec. 16), upstream through T87N, R34W, Sec. 35.

4. Lake Creek from its confluence with the North Raccoon River (T86N, R34W, Sec. 23), upstream through T87N, R33W, Sec. 25.

5. Purgatory Creek from its confluence with the North Raccoon River (T84N, R33W, Sec. 11), upstream through T86N, R32W, Sec. 17.

6a. Cedar Creek from its confluence with the North Raccoon River (T85N, R32W, Sec. 33), upstream to the confluence of West Cedar Creek and East Cedar Creek (T87N, R31W, Sec. 31).

6b. West Cedar Creek from its confluence with East Cedar Creek (T87N, R31W, Sec. 31), upstream through T87N, R31W, Sec. 18.

6c. East Cedar Creek from its confluence with West Cedar Creek (T87N, R31W, Sec. 31), upstream through T87N, R31W, Sec. 9.

7. Short Creek from its confluence with the North Raccoon River (T84N, R31W, Sec. 33), upstream through T84N, R31W, Sec. 28.

8. Hardin Creek from its confluence with the North Raccoon River (T83N, R30W, Sec. 23), upstream through T85N, R31W, Sec. 27.

9a. Buttrick Creek from its confluence with the North Raccoon River (T83N, R30W, Sec. 26), upstream to the confluence of West

Buttrick Creek and East Buttrick Creek (T84N, R30W, Sec. 25).

9b. West Buttrick Creek, from its confluence with East Buttrick Creek (T84N, R30W, Sec. 25), upstream through T86N, R30W, Sec. 3.

9c. East Buttrick Creek, from its confluence with West Buttrick Creek (T84N, R30W, Sec. 25), upstream through T85N, R29W, Sec. 20.

10a. Elm Branch from its confluence with the North Raccoon River (T81N, R28W, Sec. 28), upstream to its confluence with Swan Lake Branch T81N, R28W, Sec. 28.

10b. Swan Lake Branch from its confluence with Elm Branch (T81N, R28W, Sec. 28), upstream through T80N, R28W, Sec. 4.

11. Off-channel and side-channel pools (that meet the previously described criteria) adjacent to the North Raccoon River from U.S. Highway 6 (T79N, R27W, Sec. 32), upstream to U.S. Highway 20 (T88N, R36W, Sec. 24).

(6) Map 2 follows:

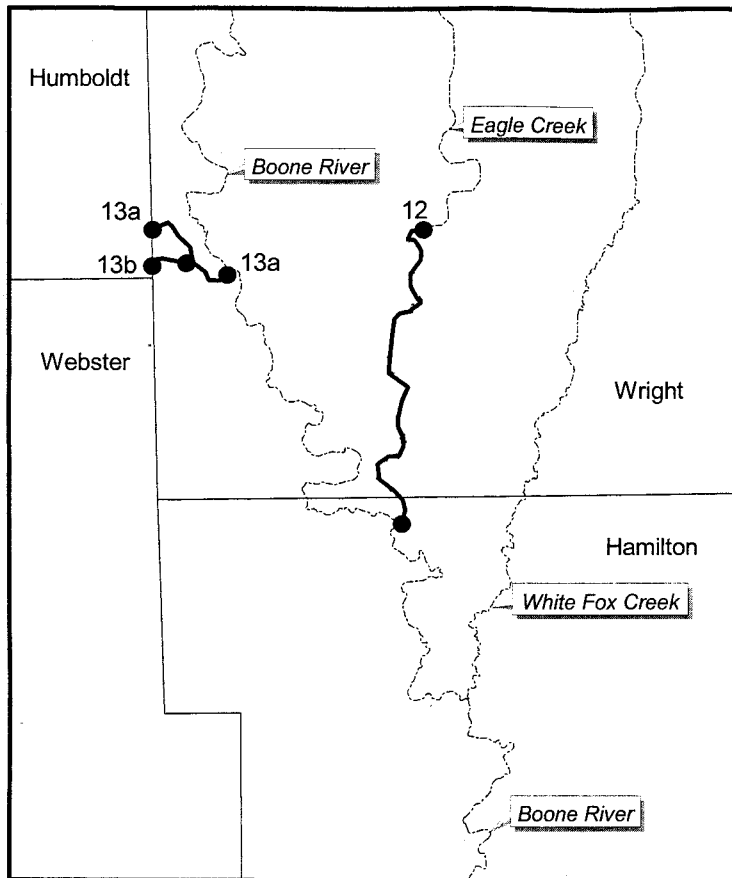
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Map 2

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

Iowa - Boone River Watershed

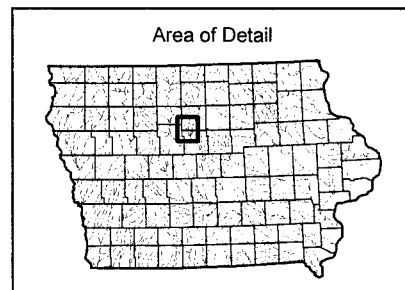


Reaches

- 12. Eagle Creek
- 13a. Ditch 3
- 13b. Ditch 19

5 0 5 Miles

- Proposed Critical Habitat
- Not Proposed as Critical Habitat
- County Lines



DISCLAIMER

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12. Eagle Creek from its confluence with the Boone River (T89N, R25W, Sec. 6), upstream through T91N, R25W, Sec. 30.

Ditch 3 and Ditch 19 Complex

13a. Ditch 3 from its confluence with the Boone River (T91N, R26W, Sec. 32), upstream through T91N, R26W, Sec. 30.

13b. Ditch 19 from its confluence with Ditch 3 (T91N, R26W, Sec. 31), upstream through T91N, R26W, Sec. 31.
(7) Map 3 follows:

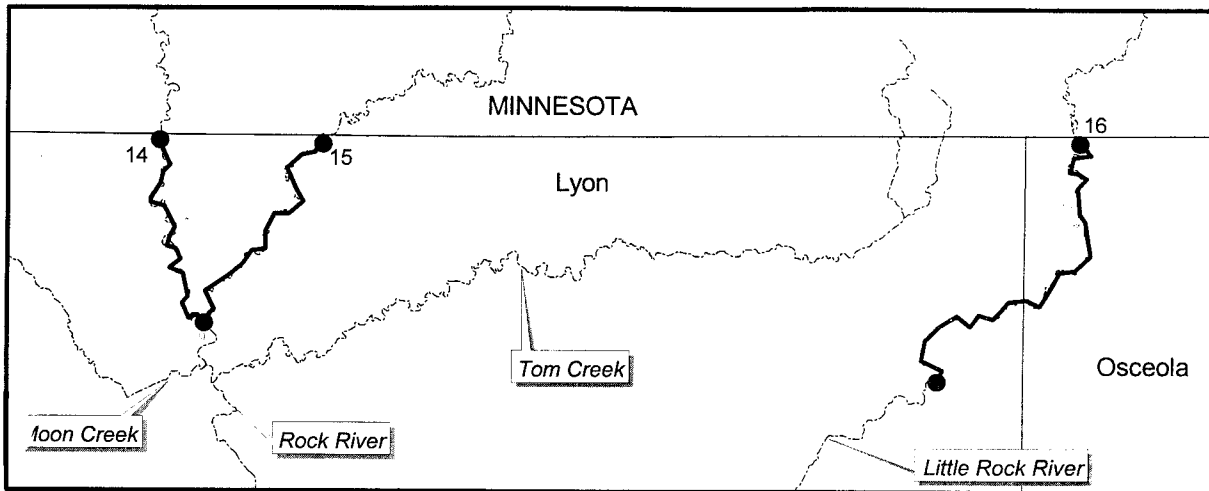
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Map 3

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

Iowa - Rock River Watershed

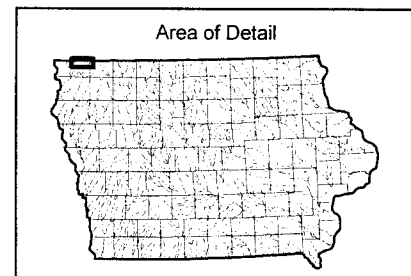


5 0 5 Miles

Reaches

- 14. Rock River
- 15. Kanaranzi Creek
- 16. Little Rock River

- Proposed Critical Habitat
- Not Proposed as Critical Habitat
- County Lines



CLAIMER

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Rock River Complex

14. Rock River from its confluence with Kanaranzi Creek (T100N, R45W, Sec. 28), upstream to the Iowa/Minnesota State border (T100N, R45W, Sec. 8).

15. Kanaranzi Creek from its confluence with the Rock River (T100N, R45W, Sec. 28), upstream to the Iowa/Minnesota State border (T100N, R45W, Sec. 11).

Little Rock River Complex

16. Little Rock River from State Highway 9 (T100N, R43W, Sec. 34), upstream to the Iowa/Minnesota State border (T100N, R42W, Sec. 7).

(8) Map 4 follows:

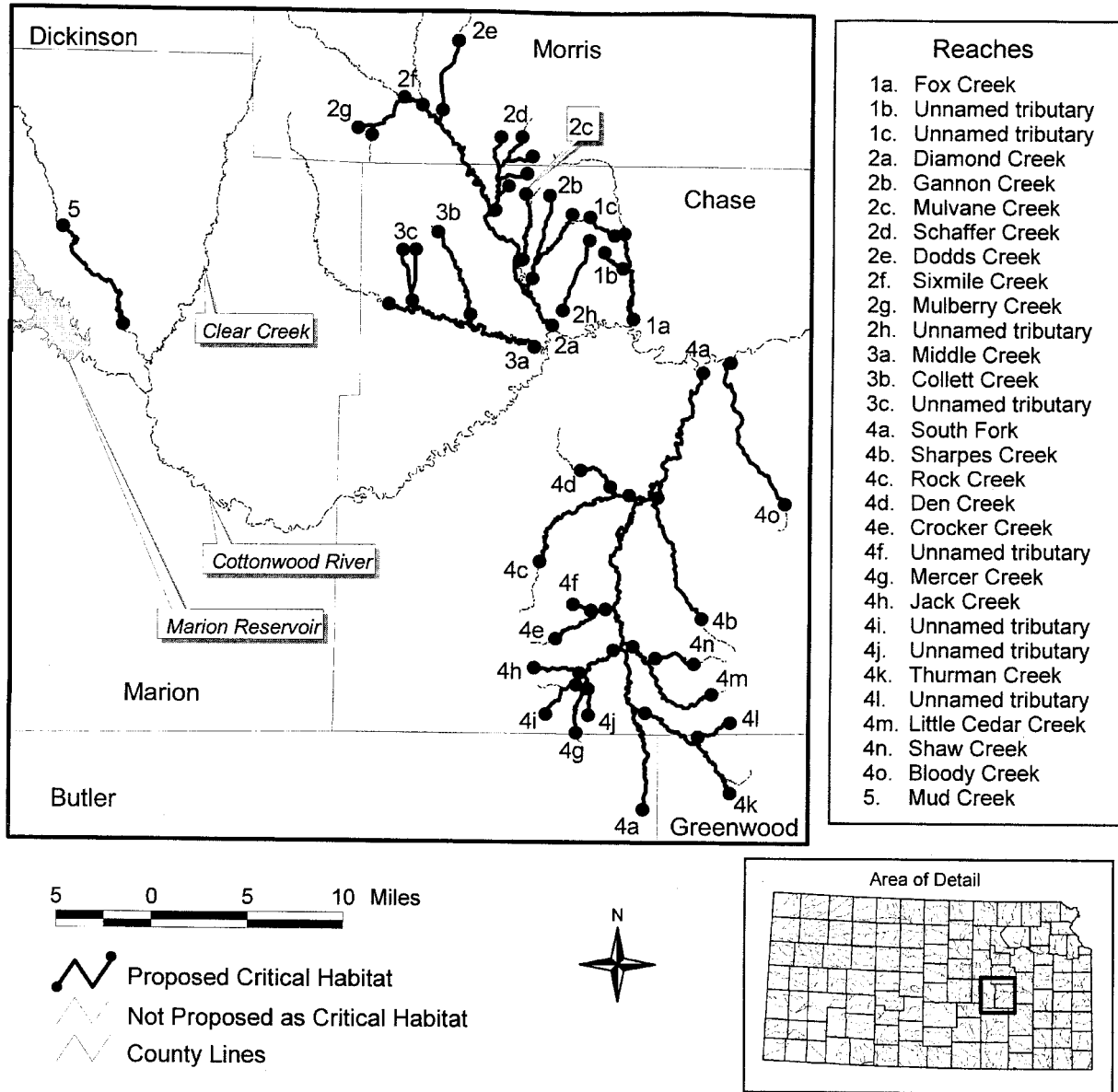
BILLING CODE 4310-55-P

Map 4

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

Kansas - Cottonwood River Watershed



CLAIMER

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Fox Creek Complex

1a. Fox Creek from U.S. Highway 50 (T19S, R8E, Sec. 17), upstream through T18S, R8E, Sec. 29.

1b. Unnamed tributary to Fox Creek, from their confluence (T18S, R8E, Sec. 32), upstream through T18S, R8E, Sec. 31.

1c. Unnamed tributary to Fox Creek, from their confluence (T18S, R8E, Sec. 29), upstream through T18S, R8E, Sec. 19.

Diamond Creek Complex

2a. Diamond Creek from U.S. Highway 50 (T19S, R7E, Sec. 14), upstream to its confluence with Sixmile Creek (T17S, R6E, Sec. 21).

2b. Gannon Creek from its confluence with Diamond Creek (T19S, R7E, Sec. 10), upstream through T18S, R7E, Sec. 24; and an unnamed tributary to Gannon Creek, from their confluence (T18S, R7E, Sec. 34), upstream through T18S, R7E, Sec. 14.

2c. Mulvane Creek from its confluence with Diamond Creek (T18S, R7E, Sec. 33), upstream through T18S, R7E, Sec. 16.

2d. Schaffer Creek from its confluence with Diamond Creek (T18S, R7E, Sec. 17), upstream through T17S, R7E, Sec. 33; an unnamed tributary stream from its confluence with Schaffer Creek (T18S, R7E, Sec. 5), upstream through T17S, R7E, Sec. 32; an unnamed tributary stream from its confluence with Schaffer Creek (T18S, R7E, Sec. 5), upstream through T18S, R7E, Sec. 3; an unnamed tributary stream from its confluence with Schaffer Creek (T18S, R7E, Sec. 8), upstream through T18S, R7E, Sec. 4; and an unnamed tributary stream from its confluence with Schaffer Creek (T18S, R7E, Sec. 8), upstream through T18S, R7E, Sec. 8.

2e. Dodds Creek from its confluence with Diamond Creek (T17S, R6E, Sec. 26), upstream through T17S, R6E, Sec. 1.

2f. Sixmile Creek from its confluence with Diamond Creek (T17S, R6E, Sec. 22), upstream to its confluence with Mulberry Creek (T17S, R6E, Sec. 21).

2g. Mulberry Creek from its confluence with Sixmile Creek (T17S, R6E, Sec. 21), upstream through T17S, R6E, Sec. 30; and an unnamed tributary to Mulberry Creek from their confluence (T17S, R6E, Sec. 30), upstream through T17S, R6E, Sec. 30.

2h. Unnamed tributary to the Cottonwood River from their confluence (T19S, R7E, Sec. 12), upstream through T18S, R8E, Sec. 30.

Middle Creek Complex

3a. Middle Creek from U.S. Highway 50 (T19S, R7E, Sec. 22), upstream to its confluence with Stribby Creek (T19S, R6E, Sec. 8).

3b. Collett Creek from its confluence with Middle Creek (T19S, R7E, Sec. 18), upstream through T18S, R6E, Sec. 26).

3c. Unnamed tributary to Middle Creek, from their confluence (T19S, R6E, Sec. 10), upstream through T18S, R6E, Sec. 33; and an unnamed tributary to the first tributary, from their confluence, upstream through T18S, R6E, Sec. 34.

South Fork of the Cottonwood River (South Fork) Complex

4a. South Fork from its confluence with the Cottonwood River (T19S, R8E, Sec. 25), upstream through T23S, R8E, Sec. 21.

4b. Sharpes Creek from its confluence with the South Fork (T20S, R8E, Sec. 34), upstream through T21S, R8E, Sec. 36.

4c. Rock Creek from its confluence with the South Fork (T20S, R8E, Sec. 33), upstream through T21S, R7E, Sec. 14.

4d. Den Creek from its confluence with Rock Creek (T20S, R8E, Sec. 31), upstream through T20S, R8E, Sec. 30.

4e. Crocker Creek from its confluence with the South Fork (T21S, R8E, Sec. 31), upstream through T22S, R7E, Sec. 1.

4f. Unnamed tributary to Crocker Creek from their confluence (T21S, R8E, Sec. 31), upstream through T21S, R8E, Sec. 31.

4g. Mercer Creek from its confluence with the South Fork (T22S, R8E, Sec. 8), upstream through T22S, R8E, Sec. 31.

4h. Jack Creek from its confluence with Mercer Creek (T22S, R8E, Sec. 18), upstream through T22S, R7E, Sec. 14.

4i. Unnamed tributary to Mercer Creek, from their confluence (T22S, R8E, Sec. 19), upstream through T22S, R7E, Sec. 26.

4j. Unnamed tributary to Mercer Creek, from their confluence (T22S, R8E, Sec. 19), upstream through T22S, R8E, Sec. 31.

4k. Thurman Creek from its confluence with the South Fork (T22S, R8E, Sec. 29), upstream through T23S, R9E, Sec. 17.

4l. Unnamed tributary to Thurman Creek, from their confluence (T23S, R8E, Sec. 1), upstream through T22S, R9E, Sec. 31.

4m. Little Cedar Creek from its confluence with the South Fork (T22S, R8E, Sec. 8), upstream through T22S, R8E, Sec. 25.

4n. Shaw Creek from its confluence with Little Cedar Creek (T22S, R8E, Sec. 16), upstream through T22S, R8E, Sec. 14.

4o. Bloody Creek from its confluence with the Cottonwood River (T19S, R9E, Sec. 29), upstream through T20S, R9E, Sec. 34.

5. Mud Creek from the south section line of T19S, R3E, Sec. 13, upstream through T18S, R3E, Sec. 28.

(9) Map 5 follows:

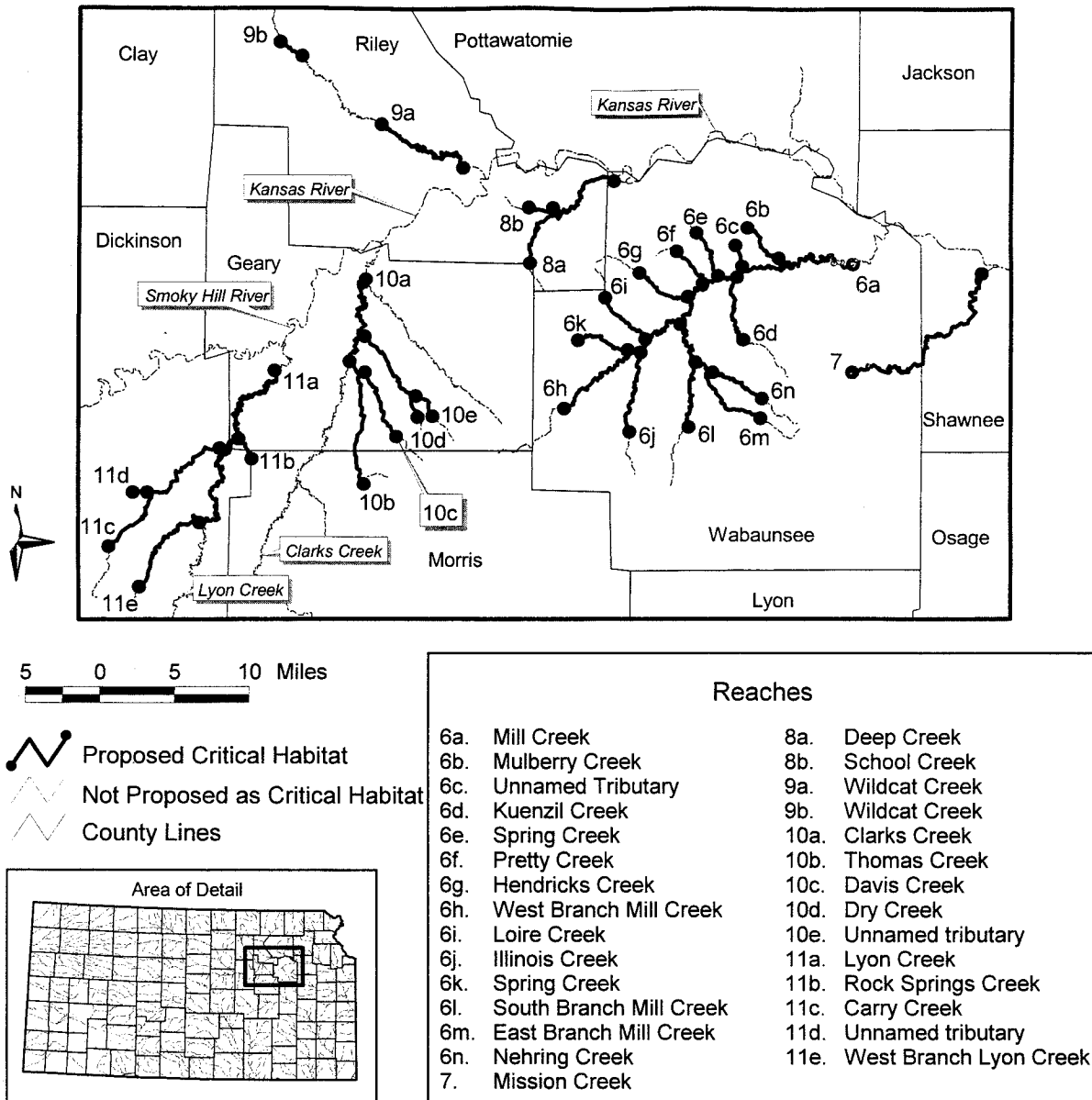
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Map 5

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

Kansas - Kansas River Watershed



CLAIMER

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Mill Creek Complex

6a. Mill Creek from Kansas Highway 30 (T11S, R12E, Sec. 26), upstream to the confluence of West Branch Mill Creek and South Branch Mill Creek (T12S, R10E, Sec. 15).

6b. Mulberry Creek from its confluence with Mill Creek (T11S, R11E, Sec. 25), upstream through T11S, R11E, Sec. 10.

6c. Spring Creek from its confluence with Mill Creek (T11S, R11E, Sec. 28), upstream through T11S, R11E, Sec. 21.

6d. Kuenzli Creek from its confluence with Mill Creek (T11S, R11E, Sec. 33), upstream through T12S, R11E, Sec. 21.

6e. Paw Paw Creek from its confluence with Mill Creek (T11S, R11E, Sec. 31), upstream through T11S, R10E, Sec. 13.

6f. Pretty Creek from its confluence with Mill Creek (T11S, R10E, Sec. 36), upstream to Kansas Highway 99 (T11S, R10E, Sec. 22).

6g. Hendricks Creek from its confluence with Mill Creek (T12S, R10E, Sec. 2), upstream through T11S, R10E, Sec. 31.

6h. West Branch Mill Creek from its confluence with South Branch Mill Creek (T12S, R10E, Sec. 15), upstream through T13S, R9E, Sec. 20.

6i. Loire Creek from its confluence with West Branch Mill Creek (T12S, R10E, Sec. 29), upstream through T12S, R9E, Sec. 11.

6j. Illinois Creek from its confluence with West Branch Mill Creek (T12S, R10E, Sec. 30), upstream through T13S, R9E, Sec. 11.

6k. Spring Creek from its confluence with West Branch Mill Creek (T12S,

R10E, Sec. 30), upstream through T12S, R9E, Sec. 21.

6l. South Branch Mill Creek from its confluence with West Branch Mill Creek (T12S, R10E, Sec. 15), upstream to Kansas Highway 4/99 (T13S, R10E, Sec. 26).

6m. East Branch Mill Creek from its confluence with South Branch Mill Creek (T12S, R10E, Sec. 35), upstream through T13S, R11E, Sec. 22.

6n. Nehring Creek from its confluence with East Branch Mill Creek (T13S, R10E, Sec. 1), upstream through T13S, R11E, Sec. 15.

7. Mission Creek from Interstate Highway 70 (T11S, R14E, Sec. 33), upstream to the confluence of North Branch Mission Creek and South Branch Mission Creek (T13S, R12E, Sec. 1).

Deep Creek Complex

8a. Deep Creek from Kansas Highway 18 (T10S, R9E, Sec. 26), upstream to Interstate Highway 70 (T11S, R8E, Sec. 26).

8b. School Creek from its confluence with Deep Creek (T11S, R9E, Sec. 6), upstream through T11S, R8E, Sec. 2.

Wildcat Creek Complex

9a. Wildcat Creek from Kansas Highway 18/Ft. Riley Boulevard (T10S, R7E, Sec. 24), upstream to the Ft. Riley boundary near Keats, Kansas (T10S, R6E, Sec. 1).

9b. Wildcat Creek from the Ft. Riley boundary near Riley, Kansas (T9S, R5E, Sec. 12), upstream to U.S. Highway 77 (T9S, R5E, Sec. 3).

Clarks Creek Complex

10a. Clarks Creek from its confluence with Humboldt Creek (T11S, R6E, Sec. 35), upstream to its confluence with Thomas Creek (T12S, R6E, Sec. 34).

10b. Thomas Creek from its confluence with Clarks Creek (T12S, R6E, Sec. 34), upstream through T13S, R6E, Sec. 34.

10c. Davis Creek from its confluence with Thomas Creek (T13S, R6E, Sec. 2), upstream through T13S, R7E, Sec. 31.

10d. Dry Creek from its confluence with Clarks Creek (T12S, R6E, Sec. 23), upstream through T13S, R7E, Sec. 22.

10e. West Branch Dry Creek from its confluence with Dry Creek (T13S, R7E, Sec. 16), upstream through T13S, R7E, Sec. 21.

Lyon Creek Complex

11a. Lyon Creek from U.S. Highway 77 (T13S, R5E, Sec. 3), upstream to the confluence with West Branch Lyon Creek (T15S, R4E, Sec. 2).

11b. Rock Springs Creek from its confluence with Lyon Creek (T13S, R5E, Sec. 3), upstream through T14S, R5E, Sec. 5.

11c. Carry Creek from its confluence with Lyon Creek (T13S, R5E, Sec. 31), upstream through T15S, R3E, Sec. 10.

11d. Unnamed tributary to Carry Creek from their confluence (T14S, R4E, Sec. 19), upstream through T14S, R3E, Sec. 24.

11e. West Branch Lyon Creek from its confluence with Lyon Creek (T15S, R4E, Sec. 2), upstream through T15S, R3E, Sec. 25.

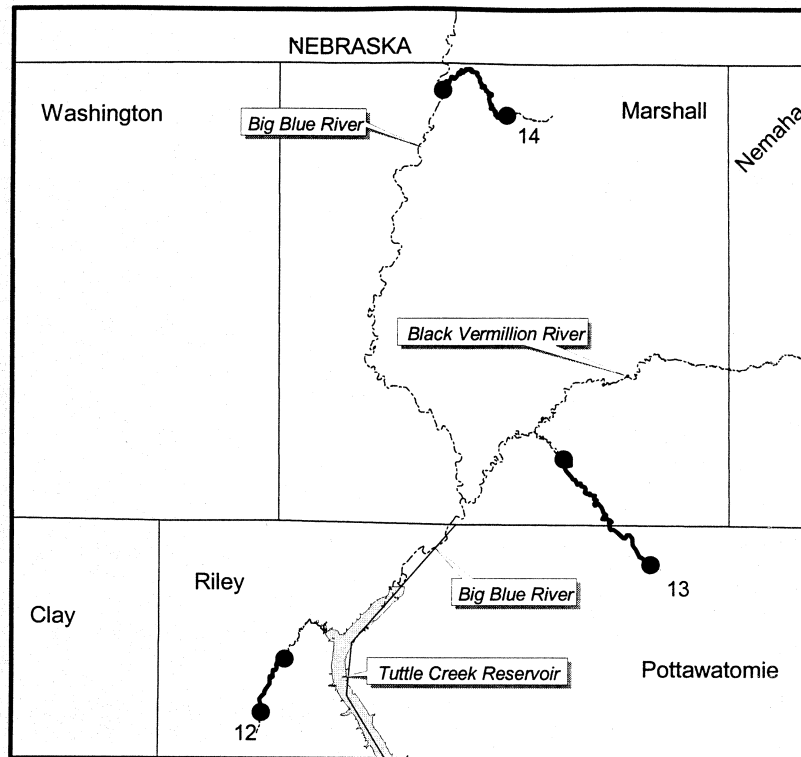
(10) Map 6 follows:

BILLING CODE 4310-55-P

Map 6

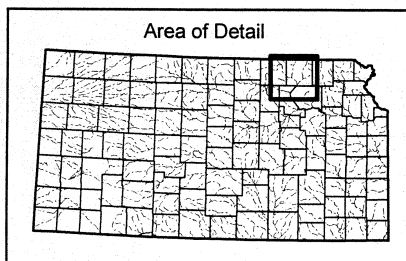
General Locations of Proposed Critical Habitat for the Topeka Shiner (*Notropis topeka*)

Kansas - Big Blue Watershed



- Proposed Critical Habitat
 Not Proposed as Critical Habitat
 County Lines

5 0 5 10 15 Miles



Reaches

- 12. Walnut Creek
- 13. Clear Fork Creek
- 14. North Elm Creek

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12. Walnut Creek from the east section line of T7S, R6E, Sec. 19, upstream through T8S, R5E, Sec. 1.

13. Clear Fork Creek from its confluence with Jim Creek (T5S, R9E,

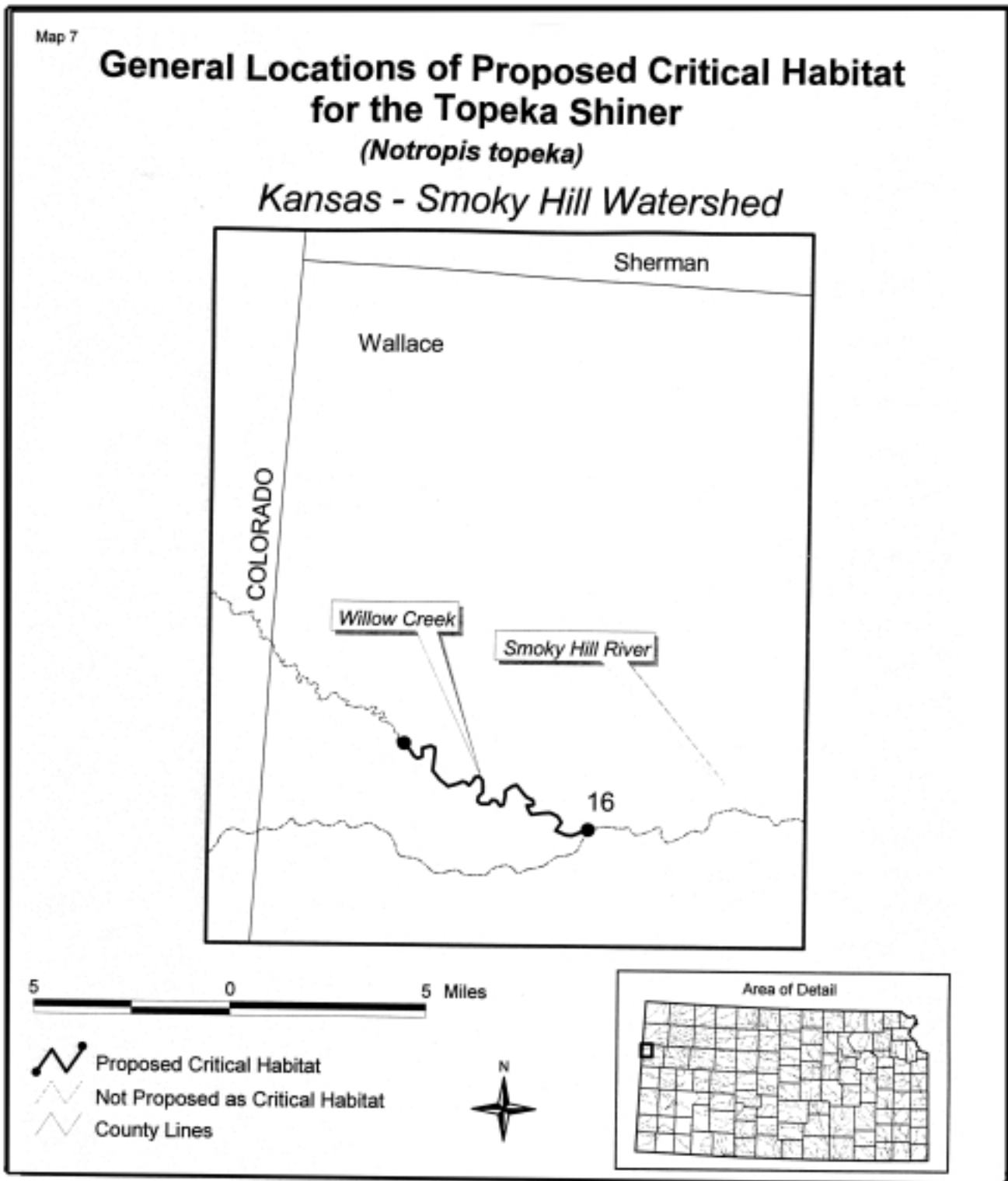
Sec. 17), upstream through T6S, R10E, Sec. 18.

14. North Elm Creek from its confluence with the Big Blue River

(T1S, R7E, Sec. 11), upstream through T1S, R8E, Sec. 21.

(11) Map 7 follows:

BILLING CODE 4310-55-P

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15. Willow Creek from its confluence with the Smoky Hill River (T13S, R41W, Sec. 17), upstream through T13S, R42W, Sec. 3.

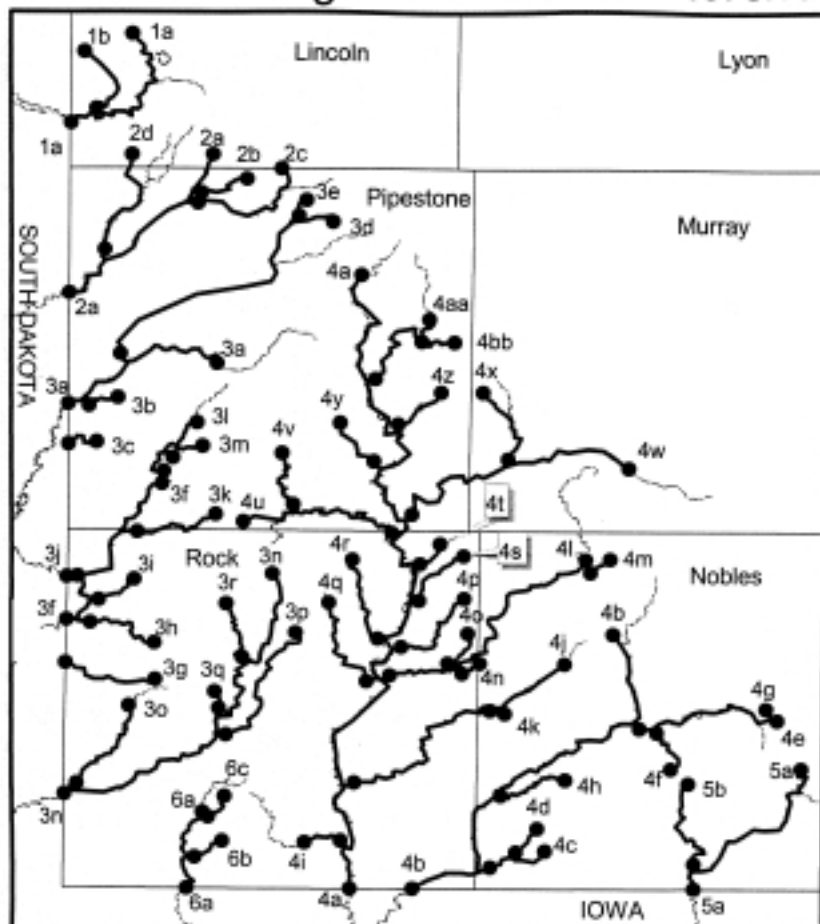
(12) Map 8 follows:

BILLING CODE 4310-55-P

Map 8

General Locations of Proposed Critical Habitat for the Topeka Shiner (*Notropis topeka*)

Minnesota - Big Sioux River Watershed



5 0 5 10 Miles



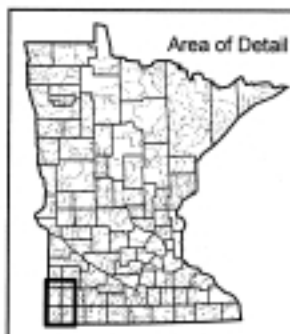
Proposed Critical Habitat



Not Proposed as Critical Habitat



County Lines



Reaches

- 1a. Medary Creek
- 1b. Unnamed tributary
- 2a. Flandreau Creek
- 2b. Unnamed tributary
- 2c. East Branch Flandreau Creek
- 2d. Willow Creek
- 3a. Pipestone Creek
- 3b. Unnamed tributary
- 3c. Unnamed tributary
- 3d. North Branch Pipestone Creek
- 3e. Unnamed tributary
- 3f. Split Rock Creek
- 3g. Unnamed tributary
- 3h. Unnamed tributary
- 3i. Unnamed tributary
- 3j. Pipestone Creek
- 3k. Unnamed tributary
- 3l. Split Rock Creek
- 3m. Unnamed tributary
- 3n. Beaver Creek
- 3o. Springwater Creek
- 3p. Little Beaver Creek
- 3q. Unnamed tributary
- 3r. Unnamed tributary
- 4a. Rock River
- 4b. Kanaranz Creek
- 4c. Norwegian Creek
- 4d. Unnamed tributary
- 4e. East Branch Kanaranz Creek
- 4f. Unnamed tributary
- 4g. Unnamed tributary
- 4h. Unnamed tributary
- 4i. Ash Creek
- 4j. Elk Creek
- 4k. Unnamed tributary
- 4l. Champepadan Creek
- 4m. Unnamed tributary
- 4n. Unnamed tributary
- 4o. Unnamed tributary
- 4p. Unnamed tributary
- 4q. Mound Creek
- 4r. Unnamed tributary
- 4s. Unnamed tributary
- 4t. Unnamed tributary
- 4u. Popular Creek
- 4v. Unnamed tributary
- 4w. Chanarambie Creek
- 4x. North Branch Chanarambie Cr.
- 4y. Unnamed tributary
- 4z. Unnamed tributary
- 4aa. East Branch Rock River
- 4bb. Unnamed tributary
- 5a. Little Rock River
- 5b. Little Rock Creek
- 6a. Mud Creek
- 6b. Unnamed tributary
- 6c. Unnamed tributary

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Medary Creek Complex

1a. Medary Creek from the MN/SD state border (T109N, R47W, Sec. 13), upstream through T110N, R46W, Sec. 21.

1b. Unnamed tributary to Medary Creek, from their confluence (T109N, R46W, Sec. 18), upstream through T110N, R46W, Sec. 30.

Flandreau Creek Complex

2a. Flandreau Creek from the Minnesota/South Dakota State border (T107N, R47W, Sec. 13), upstream through (T109N, R45W, Sec. 31).

2b. Unnamed tributary to Flandreau Creek, from their confluence (T108N, R46W, Sec. 11), upstream through T108N, R45W, Sec. 6.

2c. East Branch Flandreau Creek from its confluence with Flandreau Creek (T108N, R46W, Sec. 14), upstream through T108N, R45W, Sec. 4.

2d. Willow Creek from its confluence with Flandreau Creek (T107N, R46W, Sec. 6), upstream through T109N, R46W, Sec. 3.

Split Rock/Pipestone/Beaver Creek Complex

3a. Pipestone Creek from the Minnesota/South Dakota State border (T106N, R47W, Sec. 23), upstream through T106N, R46W, Sec. 1.

3b. Unnamed tributary to Pipestone Creek, from their confluence (T106N, R47W, Sec. 24), upstream through T106N, R46W, Sec. 19.

3c. Unnamed tributary to Pipestone Creek, from the Minnesota/South Dakota State border (T105N, R47W, Sec. 2), upstream through T105N, R46W, Sec. 1.

3d. North Branch Pipestone Creek from its confluence with Pipestone Creek (T107N, R46W, Sec. 5), upstream through T108N, R45W, Sec. 23.

3e. Unnamed tributary to North Branch Pipestone Creek, from their confluence (T108N, R45W, Sec. 22), upstream through T108N, R45W, Sec. 15.

3f. Split Rock Creek from the Minnesota/South Dakota State border (T103N, R47W, Sec. 2), upstream to Split Rock Lake Outlet (T105N, R46W, Sec. 20).

3g. Unnamed tributary to Split Rock Creek from the Minnesota/South Dakota State border (T103N, R47W, Sec. 23), upstream through T103N, R46W, Sec. 29.

3h. Unnamed tributary to Split Rock Creek, from their confluence (T103N, R47W, Sec. 2), upstream through T103N, R46W, Sec. 8.

3i. Unnamed tributary to Split Rock Creek, from their confluence (T104N,

R47W, Sec. 25), upstream through T104N, R46W, Sec. 19.

3j. Pipestone Creek from its confluence with Split Rock Creek (T104N, R47W, Sec. 23), upstream to the Minnesota/South Dakota State border (T104N, R47W, Sec. 23).

3k. Unnamed tributary to Split Rock Creek, from their confluence (T104N, R46W, Sec. 6), upstream through T105N, R46W, Sec. 36.

3l. Split Rock Creek from the headwater of Split Rock Lake (T105N, R46W, Sec. 15), upstream through T106N, R46W, Sec. 35.

3m. Unnamed tributary to Split Rock Creek, from their confluence (T105N, R46W, Sec. 3), upstream through T105N, R46W, Sec. 2.

3n. Beaver Creek from the Minnesota/South Dakota State border (T102N, R47W, Sec. 35), upstream through T104N, R45W, Sec. 20.

3o. Springwater Creek from its confluence with Beaver Creek (T102N, R47W, Sec. 35), upstream through T102N, R46W, Sec. 6.

3p. Little Beaver Creek from its confluence with Beaver Creek (T102N, R46W, Sec. 12), upstream through T103N, R45W, Sec. 9.

3q. Unnamed tributary to Beaver Creek, from their confluence (T102N, R46W, Sec. 1), upstream through T103N, R46W, Sec. 35.

3r. Unnamed tributary to Beaver Creek, from their confluence (T103N, R45W, Sec. 18), upstream through T104N, R46W, Sec. 36.

Rock River Complex

4a. Rock River from the Minnesota/Iowa State border (T101N, R45W, Sec. 36), upstream through T107N, R44W, Sec. 7.

4b. Kanaranzi Creek from the Minnesota/Iowa State border (T101N, R44W, Sec. 33), upstream through T103N, R42W, Sec. 7).

4c. Norwegian Creek from its confluence with Kanaranzi Creek (T101N, R44W, Sec. 25), upstream through T101N, R43W, Sec. 21.

4d. Unnamed tributary to Norwegian Creek, from their confluence (T101N, R44W, Sec. 20), upstream through T101N, R44W, Sec. 16.

4e. East Branch Kanaranzi Creek from its confluence with Kanaranzi Creek (T102N, R42W, Sec. 5), upstream through T102N, R41W, Sec. 5.

4f. Unnamed tributary to East Branch Kanaranzi Creek, from their confluence (T102N, R42W, Sec. 9), upstream through T102N, R42W, Sec. 22.

4g. Unnamed tributary to East Branch Kanaranzi Creek, from their confluence (T102N, R42W, Sec. 5), upstream through T102N, R42W, Sec. 5.

4h. Unnamed tributary to Kanaranzi Creek, from their confluence (T102N, R43W, Sec. 31), upstream through T102N, R43W, Sec. 27.

4i. Ash Creek from its confluence with the Rock River (T101N, R45W, Sec. 24), upstream through T101N, R45W, Sec. 14.

4j. Elk Creek from its confluence with the Rock River (T102N, R45W, Sec. 36), upstream through T103N, R43W, Sec. 22.

4k. Unnamed tributary to Elk Creek, from their confluence (T102N, R44W, Sec. 1), upstream through T102N, R43W, Sec. 6.

4l. Champepadan Creek from its confluence with the Rock River (T103N, R44W, Sec. 29), upstream through T104N, R43W, Sec. 14.

4m. Unnamed tributary to Champepadan Creek, from their confluence (T104N, R43W, Sec. 14), upstream through T104N, R43W, Sec. 13.

4n. Unnamed tributary to Champepadan Creek, from their confluence (T103N, R44W, Sec. 23), upstream through T103N, R44W, Sec. 24.

4o. Unnamed tributary to Champepadan Creek, from their confluence (T103N, R44W, Sec. 23), upstream through T103N, R44W, Sec. 12.

4p. Unnamed tributary to the Rock River, from their confluence (T103N, R44W, Sec. 8), upstream through T104N, R44W, Sec. 26.

4q. Mound Creek from its confluence with the Rock River (T103N, R44W, Sec. 30), upstream through T104N, R45W, Sec. 35).

4r. Unnamed tributary to the Rock River, from their confluence (T103N, R44W, Sec. 7), upstream through T104N, R45W, Sec. 23.

4s. Unnamed tributary to the Rock River, from their confluence (T104N, R44W, Sec. 28), upstream through T104N, R44W, Sec. 11.

4t. Unnamed tributary to the Rock River, from their confluence (T104N, R44W, Sec. 16), upstream through T104N, R44W, Sec. 10.

4u. Poplar Creek from its confluence with the Rock River (T104N, R44W, Sec. 5), upstream through T105N, R45W, Sec. 32.

4v. Unnamed tributary to Poplar Creek, from their confluence (T105N, R45W, Sec. 27), upstream through T105N, R45W, Sec. 9.

4w. Chanarambie Creek from its confluence with the Rock River (T105N, R44W, Sec. 33), upstream through (T105N, R42W, Sec. 8).

4x. North Branch Chanarambie Creek from its confluence with Chanarambie

Creek (T105N, R43W, Sec. 8), upstream through T106N, R43W, Sec. 18.

4y. Unnamed tributary to the Rock River, from their confluence (T105N, R44W, Sec. 8), upstream through T106N, R45W, Sec. 36.

4z. Unnamed tributary to the Rock River, from their confluence (T106N, R44W, Sec. 33), upstream through T106N, R44W, Sec. 23.

4aa. East Branch Rock River from its confluence with the Rock River (T106N, R44W, Sec. 18), upstream through T107N, R44W, Sec. 27.

4bb. Unnamed tributary to East Branch Rock River, from their

confluence (T107N, R44W, Sec. 34), upstream through T107N, R44W, Sec. 35.

Little Rock River Complex

5a. Little Rock River from the Minnesota/Iowa State border (T101N, R42W, Sec. 35), upstream through T102N, R41W, Sec. 27.

5b. Little Rock Creek from its confluence with the Little Rock River (T101N, R42W, Sec. 26), upstream through T102N, R42W, Sec. 34.

Mud Creek Complex

6a. Mud Creek from the Minnesota/Iowa State border (T102N, R46W, Sec. 34), upstream thru T101N, R46W, Sec. 11.

6b. Unnamed tributary to Mud Creek, from their confluence (T101N, R46W, Sec. 22), upstream through T101N, R46W, Sec. 24.

6c. Unnamed tributary to Mud Creek, from their confluence (T101N, R46W, Sec. 10), upstream through T101N, R46W, Sec. 1.

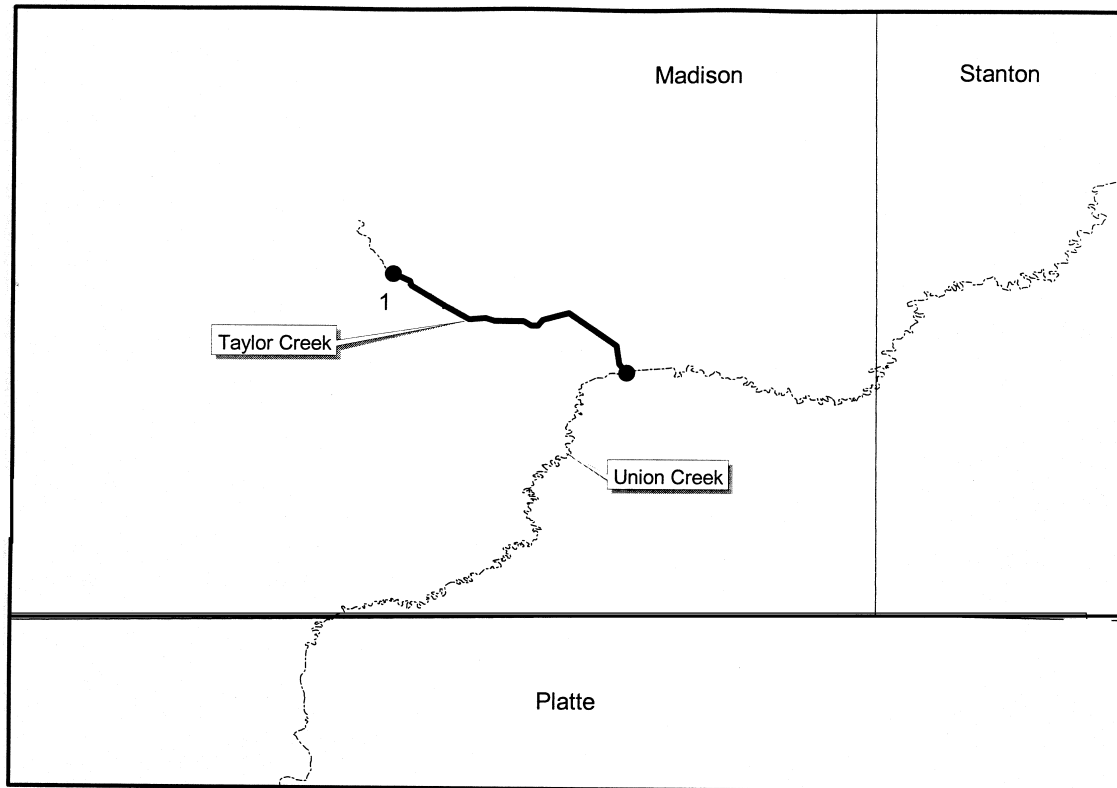
(13) Map 9 follows:

BILLING CODE 4310-55-P




Map 9

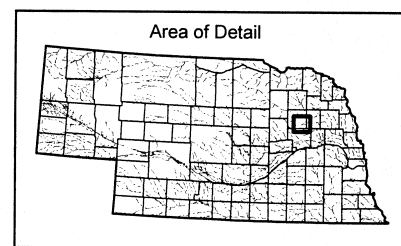
General Locations of Proposed Critical Habitat for the Topeka Shiner (*Notropis topeka*)

Nebraska - Elkhorn River Watershed



5 0 5 Miles

-  Proposed Critical Habitat
-  Not Proposed as Critical Habitat
-  County Lines



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1. Taylor Creek from its confluence with Union Creek (T22N, R1W, Sec. 32), upstream through T22N, R2W, Sec. 22.

(14) Map 10 follows:

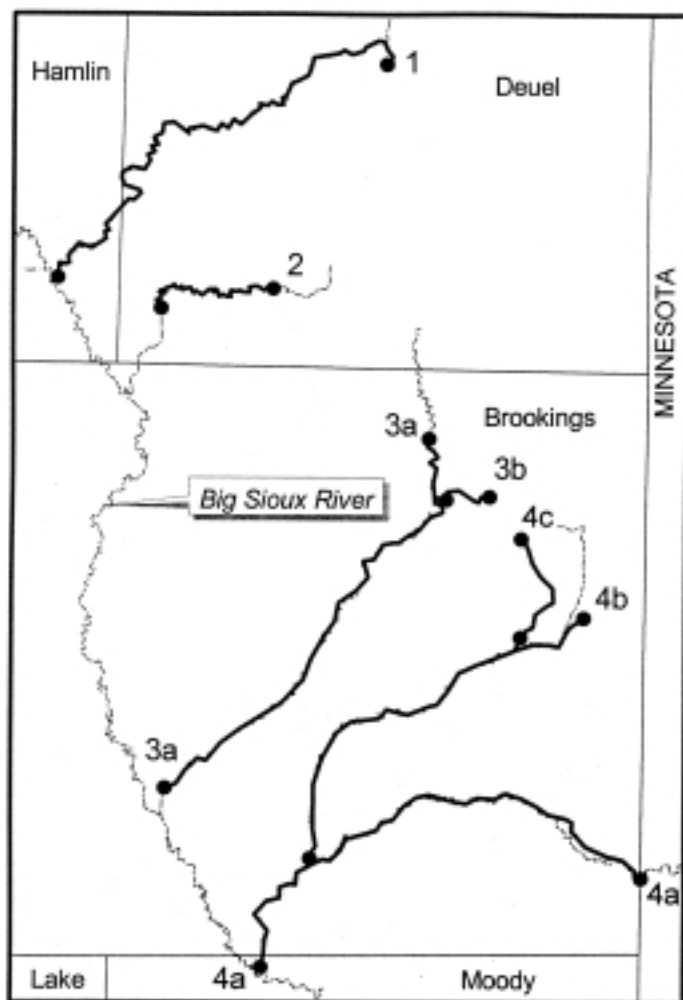
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Map 10

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

South Dakota - Upper Big Sioux Watershed



Reaches

1. Hidewood Creek
2. Peg Munky Run
- 3a. Sixmile Creek
- 3b. Unnamed tributary
- 4a. Medary Creek
- 4b. Deer Creek
- 4c. Unnamed tributary

- Proposed Critical Habitat
 Not Proposed as Critical Habitat
 County Lines



Area of Detail



DISCLAIMER

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1. Hidewood Creek from its confluence with the Big Sioux River (T113N, R51W, Sec. 15), upstream to State Highway 15 (T115N, R49W, Sec. 35).

2. Peg Munky Run from State Highway 28 (T113N, R50W, Sec. 20), upstream through T113N, R50W, Sec. 24 (near Interstate Highway 29).

Sixmile Creek Complex

3a. Sixmile Creek from T110N, R50W, Sec. 33, upstream through T112N, R48W, Sec. 19.

3b. Unnamed tributary to Sixmile Creek, from their confluence (T112N, R48W, Sec. 31), upstream through T112N, R48W, Sec. 33.

Medary Creek Complex

4a. Medary Creek from its confluence with the Big Sioux River (T108N, R49W,

Sec. 6), upstream to the SD/MN state border (T109N, R47W, Sec. 15).

4b. Deer Creek from its confluence with Medary Creek (T109N, R49W, Sec. 16), upstream through T111N, R47W, Sec. 30.

4c. Unnamed tributary to Deer Creek, from their confluence (T111N, R48W, Sec. 35), upstream through T111N, R48W, Sec. 11.

(15) Map 11 follows:

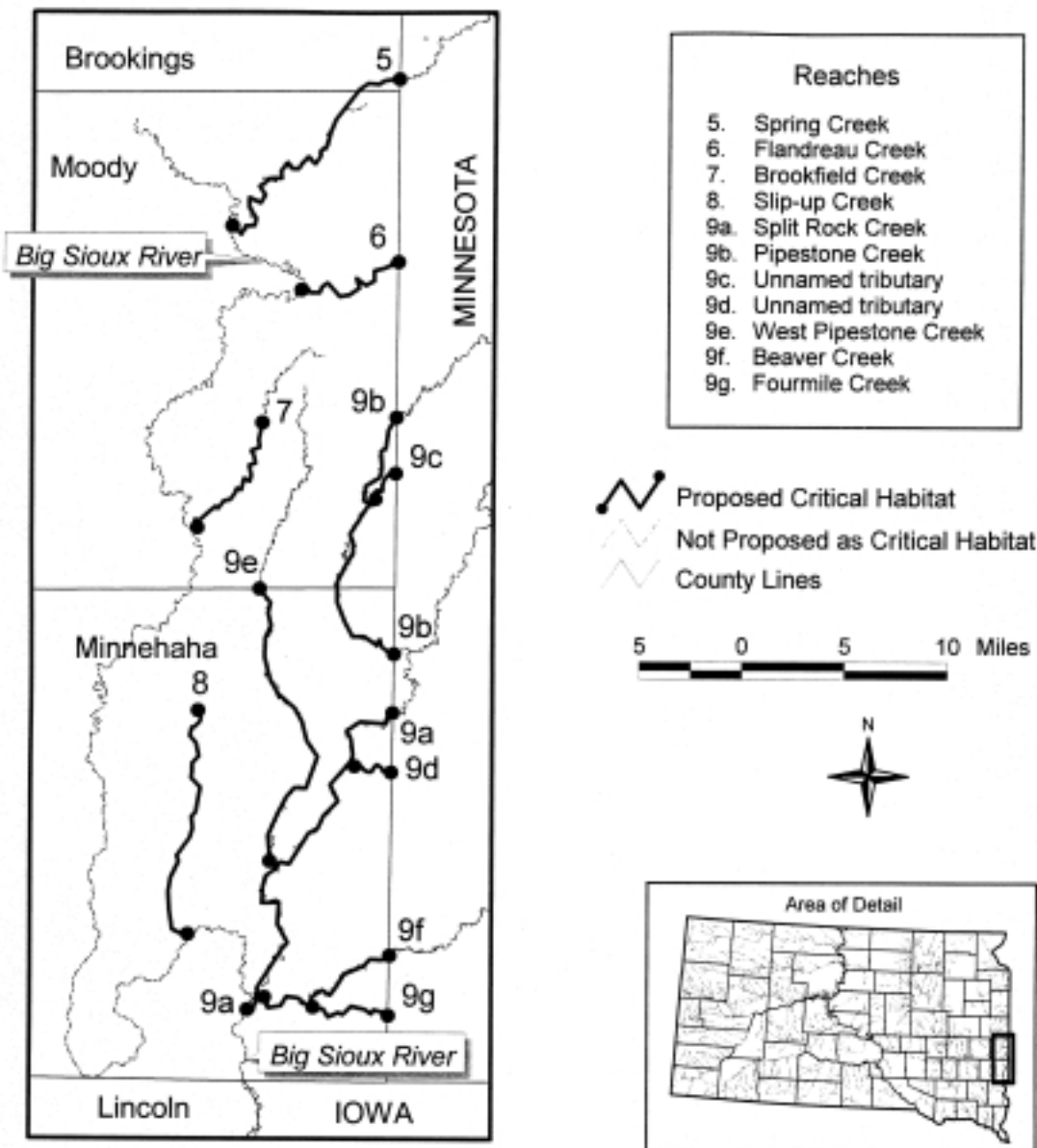
BILLING CODE 4310-55-P

Map 11

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

South Dakota - Lower Big Sioux Watershed



CLAIMER

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5. Spring Creek from its confluence with the Big Sioux River (T107N, R48W, Sec. 5), upstream to the South Dakota/Minnesota State border (T109N, R47W, Sec. 34).

Flandreau Creek Complex

6. Flandreau Creek from its confluence with the Big Sioux River (T107N, R48W, Sec. 23), upstream to the South Dakota/Minnesota State border (T107N, R47W, Sec. 15).

7. Brookfield Creek from its confluence with the Big Sioux River (T105N, R49W, Sec. 24), upstream through T106N, R48W, Sec. 28.

8. Slip-Up Creek from its confluence with the Big Sioux River (T102N, R49W, Sec. 36), upstream through T103N, R48W, Sec. 6.

Split Rock/Pipestone/Beaver Creek Complex

9a. Split Rock Creek from its confluence with the Big Sioux River (T101N, R48W, Sec. 16), upstream to the South Dakota/Minnesota State border (T103N, R47W, Sec. 3).

9b. Pipestone Creek from the South Dakota/Minnesota State border (T104N, R47W, Sec. 22), upstream to the SD/MN state border (T106N, R47W, Sec. 22).

9c. Unnamed tributary to Pipestone Creek, from their confluence (T105N, R47W, Sec. 9), upstream to the South Dakota/Minnesota State border (T105N, R47W, Sec. 3).

9d. Unnamed tributary to Split Rock Creek, from their confluence (T103N, R47W, Sec. 17), upstream to the South

Dakota/Minnesota State border (T103N, R47W, Sec. 22).

9e. West Pipestone Creek from its confluence with Split Rock Creek (T102N, R48W, Sec. 11), upstream through T104N, R48W, Sec. 3.

9f. Beaver Creek from its confluence with Split Rock Creek (T101N, R48W, Sec. 10), upstream to the South Dakota/Minnesota State border (T102N, R47W, Sec. 34).

9g. Fourmile Creek from its confluence with Beaver Creek (T101N, R48W, Sec. 13), upstream to the South Dakota/Minnesota State border (T101N, R47W, Sec. 15).

(16) Map 12 follows:

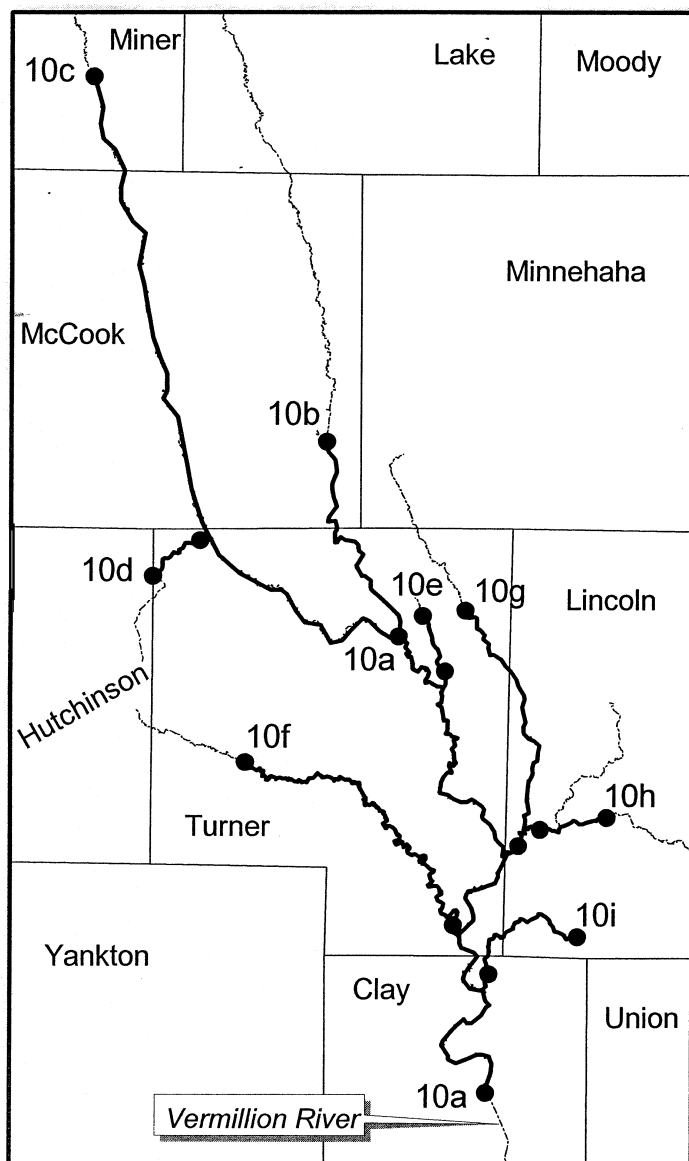
BILLING CODE 4310-55-P

Map 12

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

South Dakota - Vermillion River Watershed



Reaches

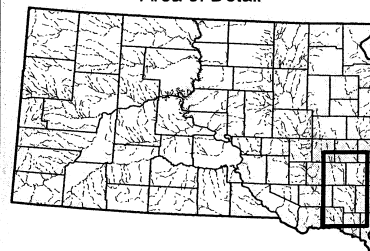
- 10a. Vermillion River
- 10b. East Fork Vermillion River
- 10c. West Fork Vermillion River
- 10d. Silver Lake Creek
- 10e. Camp Creek
- 10f. Turkey Ridge Creek
- 10g. Long Creek
- 10h. Saddle Creek
- 10i. Blind Creek

- Proposed Critical Habitat
- Not Proposed as Critical Habitat
- County Lines

5 0 5 10 15 Miles



Area of Detail



DISCLAIMER

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Vermillion River Complex

10a. Vermillion River from the southeast corner of T94N, R52W, Sec. 14, upstream to the confluence of West Fork Vermillion River and East Fork Vermillion River (T99N, R53W, Sec. 14).

10b. East Fork Vermillion River, from its confluence with the West Fork Vermillion River (T99N, R53W, Sec. 14), upstream to East Vermillion Lake Dam (T102N, R53W, Sec. 34).

10c. West Fork Vermillion River, from its confluence with the East Fork

Vermillion River (T99N, R53W, Sec. 14), upstream through T105N, R56W, Sec. 1.

10d. Silver Lake Creek from its confluence with the West Fork Vermillion River (T100N, R55W, Sec. 10), upstream to the Silver Lake outlet (T100N, R55W, Sec. 30).

10e. Camp Creek from its confluence with the Vermillion River (T99N, R52W, Sec. 32), upstream through T99N, R52W, Sec. 7.

10f. Turkey Ridge Creek from its confluence with the Vermillion River (T96N, R52W, Sec. 28), upstream through T98N, R54W, Sec. 31.

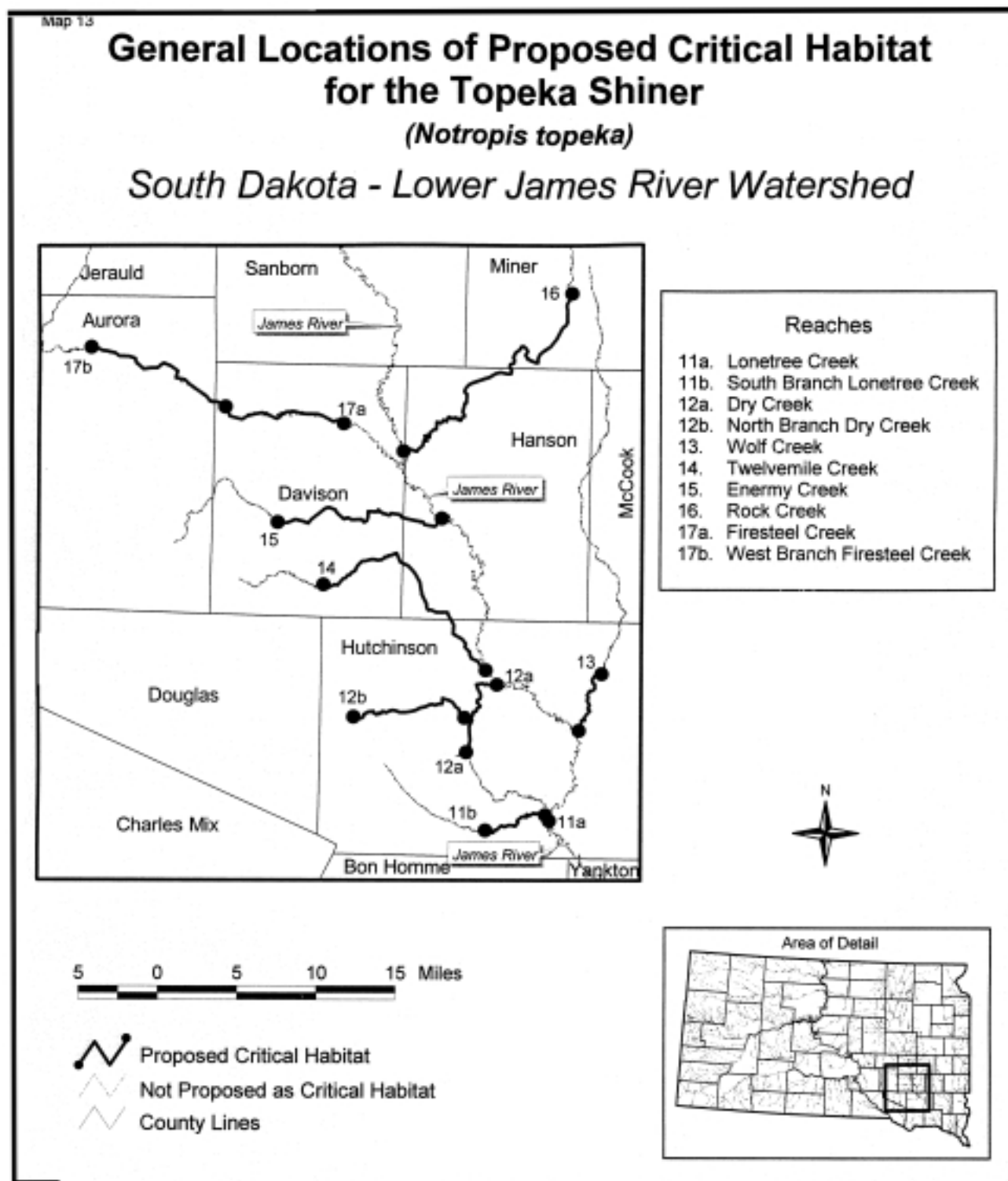
10g. Long Creek from its confluence with the Vermillion River (T97N, R51W, Sec. 31), upstream through T99N, R52W, Sec. 3.

10h. Saddle Creek from its confluence with Long Creek (T97N, R51W, Sec. 20), upstream through T97N, R50W, Sec. 18.

10i. Blind Creek from its confluence with the Vermillion River (T95N, R52W, Sec. 11), upstream through T96N, R51W, Sec. 26.

(17) Map 13 follows:

BILLING CODE 4310-55-P



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Lonetree Creek Complex

11a. Lonetree Creek from its confluence with the James River (T97N, R58W, Sec. 14), upstream to its confluence with South Branch Lonetree Creek (T97N, R58W, Sec. 10).

11b. South Branch Lonetree Creek from its confluence with Lonetree Creek (T97N, R58W, Sec. 10), upstream through T97N, R59W, Sec. 23.

Dry Creek Complex

12a. Dry Creek from its confluence with the James River (T99N, R59W, Sec. 11), upstream through T98N, R59W, Sec. 9.

12b. North Branch Dry Creek from its confluence with Dry Creek (T99N, R59W, Sec. 28), upstream through T99N, R61W, Sec. 27.

13. Wolf Creek from its confluence with the James River (T99N, R57W, Sec. 31), upstream through T99N, R57W, Sec. 4.

14. Twelvemile Creek from its confluence with the James River (T99N, R59W, Sec. 3), upstream through T101N, R61W, Sec. 23.

15. Enemy Creek from its confluence with the James River (T102N, R59W, Sec. 15), upstream through T102N, R61W, Sec. 19.

16. Rock Creek from its confluence with the James River (T103N, R60W,

Sec. 13), upstream through T106N, R57W, Sec. 34.

Firesteel Creek Complex

17a. Firesteel Creek from the east section line of T104N, R61W, Sec. 36, upstream to the confluence with West Branch Firesteel Creek (T104N, R62W, Sec. 30).

17b. West Branch Firesteel Creek from its confluence with Firesteel Creek (T104N, R62W, Sec. 30), upstream to Wilmarth Lake outlet (T105N, R64W, Sec. 31).

(18) Map 14 follows:

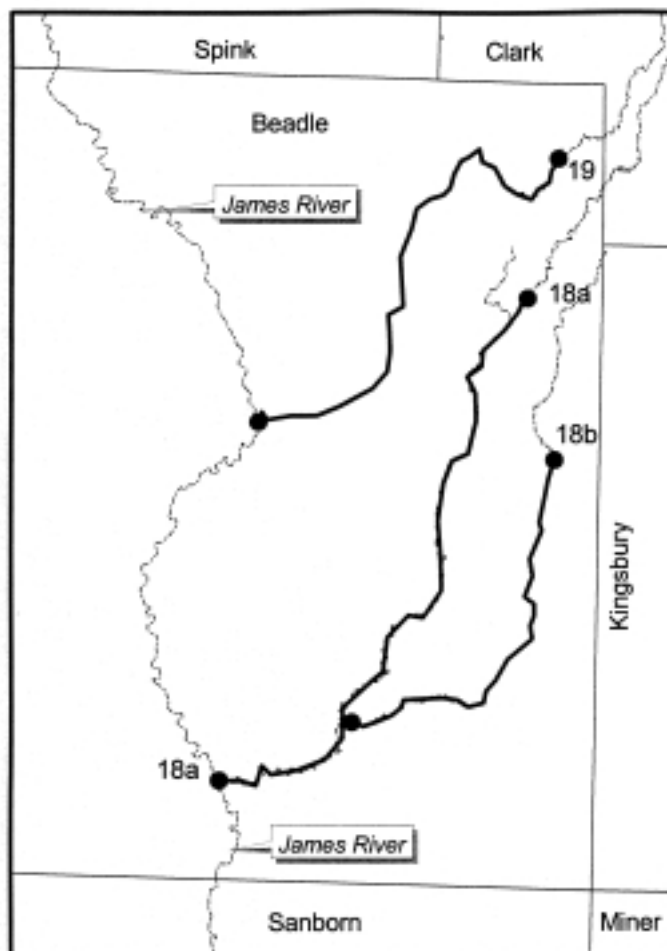
BILLING CODE 4310-55-P

Map 14

General Locations of Proposed Critical Habitat for the Topeka Shiner

(*Notropis topeka*)

South Dakota - Upper James River Watershed



Reaches

- 18a. Pearl Creek
- 18b. Middle Pearl Creek
- 19. Shue Creek



Area of Detail



5 0 5 10 Miles

- Proposed Critical Habitat
- Not Proposed as Critical Habitat
- County Lines

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<p>Pearl Creek Complex</p> <p>18a. Pearl Creek from its confluence with the James River (T109N, R61W, Sec. 15), upstream through T112N, R59W, Sec. 16.</p> <p>18b. Middle Pearl Creek from its confluence with Pearl Creek (T109N,</p>	<p>R60W, Sec. 4), upstream through T110N, R59W, Sec. 14.</p> <p>19. Shue Creek from its confluence with the James River (T111N, R61W, Sec. 11), upstream to Staum Dam (T113N, R59W, Sec. 14).</p> <p>* * * * *</p>	<p>Dated: August 12, 2002.</p> <p>Craig Manson, <i>Assistant Secretary for Fish, Wildlife, and Parks.</i></p> <p>[FR Doc. 02–20939 Filed 8–20–02; 8:45 am]</p> <p>BILLING CODE 4310–55–C</p>
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Federal Register

**Wednesday,
August 21, 2002**

Part III

Department of Housing and Urban Development

24 CFR Part 203

**Amendments to the Section 203(k)
Rehabilitation Loan Insurance Program;
Proposed Rule**

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT**
24 CFR Part 203
[Docket No. FR-4701-P-01]
RIN 2502-AH73
**Amendments to the Section 203(k)
Rehabilitation Loan Insurance Program**

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend HUD's regulations for the Section 203(k) Rehabilitation Loan Insurance Program (203(k) Program). The 203(k) Program is the Federal Housing Administration's (FHA's) primary program for the rehabilitation and repair of single family properties. First, the proposed rule would limit 203(k) rehabilitation loan insurance to one-unit structures. The proposed rule would also establish a cap on the total cost of rehabilitation. The dollar amount of the rehabilitation could not exceed 20 percent of the FHA statutory single family mortgage limit for a one-unit structure in a "high cost area." These changes would simplify the 203(k) Program for both lenders and homebuyers, and strengthen HUD's capacity to safeguard the FHA Insurance Fund.

DATES: *Comments Due Date:* October 21, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Vance T. Morris, Director, Office of Single Family Program Development, Room 9266, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-8000; telephone (202) 708-2121 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION:
**I. Background—The Section 203(k)
Rehabilitation Loan Insurance Program**

Section 203(k) of the National Housing Act (12 U.S.C. 1709(k)) authorizes HUD to insure loans for the purchase and/or rehabilitation and repair of residential properties. The 203(k) Program is HUD's primary program for the rehabilitation and repair of single family properties. Section 203(k) loan insurance enables homebuyers and homeowners to finance both the purchase (or refinancing) of a house and the cost of its rehabilitation through a single mortgage. The regulations implementing the 203(k) Program are located in 24 CFR 203.50 and 24 CFR 203.440 through 203.495. HUD's Office of Housing—Federal Housing Administration (FHA) administers the Program.

The 203(k) Program fills a unique and important role for homebuyers. In the conventional loan market, a homebuyer who purchases a home that is in need of repair or modernization usually has to follow a time-consuming and costly process. The homebuyer must obtain financing to purchase the dwelling, additional financing for the rehabilitation work, and a permanent mortgage after rehabilitation is completed to pay off the interim loans. The interim acquisition and improvement loans often have relatively high interest rates and short repayment terms. The 203(k) Program was designed to address this situation. Under this program, a homebuyer may obtain a single loan, at a long-term fixed (or variable) rate, to finance both the acquisition and rehabilitation of the property.

The extent of the rehabilitation covered by 203(k) loan insurance may range from relatively minor (though a minimum of \$5,000 in cost is required) to virtual reconstruction. For example, a home that has been demolished, or will be razed as part of rehabilitation, is eligible provided that some of the existing foundation system remains in place. Section 203(k) loan insurance can also finance the rehabilitation of the residential portion of a property that has non-residential uses.

II. This Proposed Rule

This proposed rule would make two amendments to HUD's regulations for the 203(k) Program. Specifically, the proposed rule would: (1) Limit 203(k) rehabilitation loan insurance to one-unit structures; and (2) establish a cap on the total cost of the rehabilitation. These changes would simplify the program for both lenders and homebuyers, and

strengthen HUD's capacity to safeguard the FHA Insurance Fund. This section of the preamble describes the proposed changes to the 203(k) Program.

A. Limit to One-Unit Structures

Under HUD's regulations at § 203.50(a), the 203(k) Program may be used for the rehabilitation of a one- to four-unit structure that will be used primarily for residential purposes. In addition to typical home rehabilitation projects, this program can be used to convert a one-unit structure to a two-, three-, or four-unit structure. An existing multi-unit structure can be decreased to a one- to four-unit structure. However, the regulations also require that rehabilitation loan transactions must constitute an acceptable risk, as determined by the Secretary of HUD (see § 203.50(e)).

FHA statistics show that over the past eleven years, the 203(k) Program has experienced unacceptably high default rates for multi-unit (*i.e.*, two- to four-unit) properties. The average default rate for 203(k) multi-unit properties is greater than the average default rate for multi-unit properties associated with the Section 203(b) Program (HUD's principal single family mortgage insurance program). For example, during Fiscal Years 1999 through 2001, the average default rate for two-, three-, and four-unit 203(k) properties was 32.8% greater than the average default rate for two-, three-, and four-unit properties under the 203(b) Program. To address these excessive default and claim rates, the proposed rule would amend § 203.50(e) to provide that the Secretary has determined that loan transactions for the rehabilitation of two-, three-, and four-unit structures (other than those involving the conversion of such structures to one-unit structures) constitute an unacceptable risk. This amendment would limit 203(k) loan insurance to one-unit structures. The proposed change would also prohibit the conversion of one-unit structures to two-, three-, or four-unit structures, as well as the expansion of existing two- to four-unit structures to sizes larger than a one-unit structure.

B. Cap on Total Cost of Rehabilitation

Another possible reason for the excessive claim and default rates is that the program is complex for both lenders and homebuyers, especially first time homebuyers. Since the 203(k) Program is used for rehabilitation of a property, financing under the program involves the use of contractors, consultants, engineers, and paperwork not required under other FHA insurance programs.

Simplification of the 203(k) Program will assist in reducing the number of insurance claims and comply with Congressional mandates to maintain the FHA Insurance Fund in a sound actuarial manner.

One method for reducing the complexity of the 203(k) Program is to limit the dollar amount of the rehabilitation. Currently, there is no such restriction, although the cost of the rehabilitation must be \$5,000 or greater and the overall loan amount may not exceed the limits prescribed in § 203.50(f). This proposed rule would provide that the total cost of the rehabilitation may not exceed 20 percent of the FHA statutory single family mortgage limit for a one-unit structure in a "high cost area," irrespective of location. The FHA mortgage limits are established by HUD pursuant to section 203(b)(2)(A) of the National Housing Act (12 U.S.C. 1709(b)(2)(A)). HUD announces these mortgage limits annually through a Mortgagee Letter, typically in late December for effect on January 1st of the following year. The most recent single family mortgage limits are set forth in Mortgagee Letter 01-31, issued on December 28, 2001. A copy of the Mortgagee Letter may be obtained through the HUD Web site at <http://www.hud.gov>. Under Mortgagee Letter 01-31, the maximum mortgage amount for a one-unit structure in a "high cost area" is \$261,609. The total cost of 203(k) rehabilitation would be capped at 20 percent of this amount, or \$52,321. A sampling of data available to FHA indicates that the average dollar amount of rehabilitation on a 203(k) loan in Fiscal Years 1999 and 2000 was approximately \$29,000. Accordingly, HUD believes that the proposed dollar cap on rehabilitation is appropriate to prevent the 203(k) Program from being used for overly complicated and expensive work, while continuing to serve homebuyers purchasing a one-unit structure in need of moderate rehabilitation.

The proposed cap would only include costs related to the actual rehabilitation of the property and would not include costs such as consultant fees, supplemental origination fees, the costs of preparing architectural exhibits, and contingency fees. Additionally, the cap would also exclude: (1) Rehabilitation costs incurred to improve the energy efficiency standards of the home; and (2) six months of mortgage payments.

III. Findings and Certifications

Regulatory Planning and Review

The Office of Management and Budget (OMB) reviewed this rule under Executive Order 12866, *Regulatory Planning and Review*. OMB determined that this rule is a "significant regulatory action" as defined in section 3(f) of the Order (although not an economically significant regulatory action under the Order). Any changes made to this rule as a result of that review are identified in the docket file, which is available for public inspection in the office of the Department's Rules Docket Clerk, Office of General Counsel, Room 10276, 451 Seventh Street, SW, Washington, DC 20410-0500.

Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4223). The Finding of No Significant Impact is available for public inspection between the hours of 7:30 a.m. and 5:30 p.m. weekdays in the office of the Department's Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-0500.

Regulatory Flexibility Act

The Secretary has reviewed this proposed rule before publication and by approving it certifies, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this proposed rule would not have a significant economic impact on a substantial number of small entities. The reasons for HUD's determination are as follows.

First, the proposed rule would limit 203(k) rehabilitation loan insurance to one-unit structures. Over the last eleven years, approximately 80 percent of all 203(k) loans have been made for single unit structures. Accordingly, the economic impact on small lenders of limiting the program to one-unit structures would not be significant in comparison to the total number of 203(k) loans made. In addition, although 203(k) loan insurance would no longer be available for the rehabilitation of multi-unit structures, there are other FHA mortgage insurance products that can be used for the rehabilitation of such structures. For example, FHA's Title I program can be used to improve a multi-unit structure after purchase. Nothing in this proposed rule would preclude lenders participating in the

FHA programs from offering such alternate mortgage insurance products.

The proposed rule would also cap the total cost of rehabilitation to 20 percent of the HUD single family mortgage limit for a one-unit structure in a "high cost area." As noted above in this preamble, the average amount of rehabilitation on a 203(k) loan in Fiscal Years 1999 and 2000 was approximately \$29,000. Accordingly, HUD believes that the proposed rehabilitation cap of \$52,321 is appropriate to prevent the 203(k) Program from being used for overly complicated and expensive work, while continuing to serve the program's primary customer—homebuyers purchasing a one-unit structure in need of moderate rehabilitation.

Finally, as the HUD mortgage limits increase each year, the dollar amount of the proposed cap will also rise. For example, the FHA statutory single family mortgage limit for a one-unit structure in a high-cost area rose over 9 percent from 2001 (\$239,250) to 2002 (\$261,609).

HUD has taken other steps to help ensure that the proposed cap does not impose a substantial economic burden on either 203(k) lenders or borrowers. For example, the proposed cap would only include costs related to the actual rehabilitation of the property and would not include costs such as consultant fees, supplemental origination fees, the costs of preparing architectural exhibits, and contingency fees. Additionally, the cap would not include rehabilitation costs incurred to improve the energy efficiency standards of the home and six months of mortgage payments.

Notwithstanding HUD's determination that this rule will not have a significant economic effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule would not have federalism implications and would not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This proposed rule would not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance Number for the Section 203(k) Rehabilitation Loan Insurance program is 14.108.

List of Subjects in 24 CFR Part 203

Hawaiian Natives, Home improvement, Indians—lands, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

Accordingly, for the reasons described in the preamble, HUD proposes to amend 24 CFR part 203 as follows:

PART 203—SINGLE FAMILY MORTGAGE INSURANCE

1. The authority citation for 24 CFR part 203 continues to read as follows:

Authority: 12 U.S.C. 1709, 1710, 1715b, and 1715u; 42 U.S.C. 3535(d).

2. Amend § 203.50 by revising paragraph (e) and adding paragraph (m) to read as follows:

§ 203.50 Eligibility of rehabilitation loans.

* * * * *

(e)(1) The loan transaction shall be an acceptable risk as determined by the Secretary.

(2) The Secretary has determined that loan transactions for the rehabilitation of two-, three-, and four-unit structures (other than those involving the conversion of such structures to one-unit structures) constitute an unacceptable risk.

* * * * *

(m) *Maximum cost of rehabilitation.* For purposes of paragraph (f) of this

section, the maximum cost of the rehabilitation shall not exceed 20 percent of the loan dollar amount limitation established by HUD pursuant to section 203(b)(2)(A) of the National Housing Act (12 U.S.C. 1709(b)(2)(A)) for a one-unit structure in a “high cost area.” This limit does not apply to:

(1) Costs incurred to improve the energy efficiency standards of the property;

(2) Six months of mortgage payments; and

(3) Costs not directly related to the physical rehabilitation of the property, such as (but not limited to):

(i) Consultant fees;

(ii) Supplemental origination fees;

(iii) The costs of preparing architectural exhibits; and

(iv) Contingency fees.

Dated: July 8, 2002.

John C. Weicher,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 02–21228 Filed 8–20–02; 8:45 am]

BILLING CODE 4210–27–P



Federal Register

**Wednesday,
August 21, 2002**

Part IV

Department of Housing and Urban Development

24 CFR Part 203

**Schedule for Submission of One-Time and
Up-Front Mortgage Insurance Premiums;
Proposed Rule**

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 203

[Docket No. FR-4690-P-01]

RIN 2502-AH64

Schedule for Submission of One-Time and Up-Front Mortgage Insurance Premiums

AGENCY: Office of Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: Mortgage insurance premiums ("MIPs") in many of HUD's single family mortgage insurance programs are paid at the beginning of the mortgage, as either a "one-time" or "up-front" payment. Since 1993, HUD has required that all up-front MIPs be paid electronically through automated clearinghouses. One-time MIPs are also paid electronically. Given the electronic processing of payments, which requires only a short time period, a 15 calendar day period in which to remit the funds is no longer necessary, and shortening the period would result in increased efficiencies within the mortgage insurance programs. In addition, some lenders have misused MIP funds during the 15-day period. Therefore, this rule proposes to shorten the remittance period from 15 calendar days to three business days (Monday through Friday, exclusive of Federal holidays) for both one-time and up-front MIPs.

In addition, there is some confusion about when the remittance time period begins. Therefore, this rule proposes a more precise definition of when the remittance period begins.

DATES: *Comment Due Date:* October 21, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this rule to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410-0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Vance T. Morris, Director, Office of Single Family Program Development, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, at (202) 708-

2121. Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Information Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION:

A. Background

Section 203(c)(1) of the National Housing Act authorizes the Secretary to set the premium charge for insurance of mortgages under Title II of the National Housing Act. In a June 23, 1983, final rule (48 FR 28804) that followed a proposed rule and public comment, HUD established the one-time MIP for single-family programs, citing improved cash management for HUD without increased burdens on borrowers. The specific programs affected by this one-time MIP are listed in 24 CFR 203.259a, and include loans for refinancing loans insured under the National Housing Act (*see* 24 CFR 203.43(c)); mortgages in Hawaiian Home Lands (*see* 24 CFR 203.43i); and loans which are obligations of the Mutual Mortgage Insurance fund, which were executed before July 1, 1991.

Under the implementing rule for the one-time MIP, at 24 CFR 203.280—203.283, mortgagees in the affected programs pay the entire premium for the borrower within 15 days of closing. The rule generally contemplates that borrowers would amortize the mortgage insurance premium over the life of the loan, and that the premium amount would be calculated based on actuarial factors including the mortgage term and the costs projected by HUD discounted at a rate based on the expected rate of return of the mortgage insurance fund's investments. (*See* 48 FR 28795.)

Section 203(c)(2) of the National Housing Act authorizes the up-front MIP, implemented at 24 CFR 203.284, which applies to all other mortgages executed on or after July 1, 1991 that are obligations of the Mutual Mortgage Insurance Fund. The up-front MIP requires the payment of a single premium of up to 2.25 percent of the original insured principal balance of the mortgage, and annual payments of .50 percent of the remaining insured principal balance for stated periods of time that vary depending on the original principal obligation of the mortgage.

HUD's regulations at 24 CFR 203.280 state that, for mortgages in which a one-time MIP is charged, the payment shall be made within 15 days of closing. In addition, up-front MIPs under 24 CFR 203.284 and 203.285 are subject to the same 15-day requirement. *See* 24 CFR 203.284(f) and 203.285(c), incorporating 24 CFR 203.280 by cross-reference.

Since April 7, 1993, it has been mandatory for lenders to make up-front MIP payments in the single-family insurance program through an electronic system. (*See, e.g.,* Mortgagee Letter 94-25.) The one-time MIP is remitted electronically as well. (*See, e.g.,* Mortgagee Letter 96-33.) In such an environment, where the funds are transmitted within a few moments rather than by mailing, it is no longer necessary for the lender to retain the funds beyond a brief period for accounting purposes. Furthermore, there have been some instances of MIP premium monies being misused by some lenders during the 15-day period, and earlier remittance should eliminate this problem while improving the cash flow of the insurance fund.

B. This Proposed Rule

This proposed rule would amend 24 CFR 203.280 and 203.282 to reduce the remittance period for the up-front and one-time MIP in affected single-family programs from 15 calendar days to 3 business days, and to adjust the late charge provisions accordingly. Business days are Monday through Friday, excluding Federal holidays. In addition, the rule provides that in the case of refinancings, the three-day period will be counted from the date of disbursement of the mortgage proceeds rather than the loan closing.

Findings and Certifications

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this proposed rule, and in so doing certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule imposes no new obligations of any kind, but only shortens the timing of an existing obligation to remit one-time and up-front mortgage insurance premiums. Because these premiums are remitted electronically, very little remittance time is actually required. This rule should impose no significant burdens on business.

Notwithstanding HUD's determination that this rule does not have a significant economic impact on a substantial number of small entities, HUD specifically invites comment regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in the preamble.

Environmental Impact

This proposed rule does not direct, provide for assistance of loan and

mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on State and local governments and is not required by statute, or preempts State law, unless the relevant requirements of section 6 of the Executive Order are met. This rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4; approved March 22, 1995) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This proposed rule does not

impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number applicable to this rule is 14.117.

List of Subjects for 24 CFR Part 203

Hawaiian Natives, Home improvement, Indians—lands, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

For the reasons stated in the preamble, HUD amends 24 CFR part 203 as follows:

PART 203—SINGLE FAMILY HOUSING MORTGAGE INSURANCE

1. The authority citation for 24 CFR part 203 continues to read as follows:

Authority: 12 U.S.C. 1709, 1710, 1715b, and 1715u; 42 U.S.C. 3535(d).

Subpart B—Contract Rights and Obligations

2. Revise 24 CFR 203.280 to read as follows:

§ 203.280 One-time or up-front MIP.

(a) For mortgages for which a one-time or up-front MIP is to be charged in accordance with §§ 203.259a, 203.284, or § 203.285, the mortgagee shall, as a condition to the endorsement of the mortgage for insurance, pay to the Commissioner for the account of the

mortgagor, in a manner prescribed by the Commissioner, a premium representing the total obligation for the insuring of the mortgage by the Commissioner or the up-front portion of the total obligation, as applicable, within three business days of the date of closing, or, in the case of a refinancing transaction, within three business days from the date of disbursement of the mortgage proceeds.

(b) For purposes of this section, "business days" means Monday through Friday, exclusive of Federal holidays.

3. Revise 24 CFR 203.282 to read as follows:

§ 203.282 Mortgagee's late charge and interest.

(a) Payment of a one-time or up-front MIP is late if not received by HUD within three business days after the closing, or the disbursement of the loan funds in a refinancing transaction. Late payments shall include a late charge of four percent of the amount of the MIP.

(b) If payment of the MIP is not received by HUD within 30 days after the closing, or the disbursement of the loan funds in a refinancing transaction, the mortgagee will be charged additional late fees until payment is received at an interest rate set in conformity with the Treasury Fiscal Requirements Manual.

Dated: July 8, 2002.

John C. Weicher,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 02-21227 Filed 8-20-02; 8:45 am]

BILLING CODE 4210-27-P



Federal Register

**Wednesday,
August 21, 2002**

Part V

Department of Housing and Urban Development

24 CFR Part 234

**FHA Approval of Condominium
Developments Located in the
Commonwealth of Puerto Rico for
Mortgage Insurance Under the Section
234(c) Program; Proposed Rule**

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 234

[Docket No. FR-4713-P-01]

RIN 2502-AH80

FHA Approval of Condominium Developments Located in the Commonwealth of Puerto Rico for Mortgage Insurance Under the Section 234(c) Program

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Department's regulations with respect to condominium ownership mortgage insurance to provide that the date of recordation for purposes of obtaining Federal Housing Administration (FHA) approval of a condominium development in the Commonwealth of Puerto Rico for mortgage insurance under the Section 234(c) program is the date the condominium legal documents are presented to the Commonwealth Registry of the Property. The Department believes that the proposed change will improve homeownership opportunities through increased FHA activity under the Section 234(c) program.

DATES: *Comment Due Date:* October 21, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this rule to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Vance Morris, Office of the Deputy Assistant Secretary for Single Family Housing, Room 9278, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Telephone (202) 708-2121 ext. 2204 (this is not a toll-free number). Hearing- or speech-impaired persons may access this number by calling the Federal Information Relay Service at 1-800-877-8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 234(c) of the National Housing Act (12 U.S.C. 1715y(c)) (Act) authorizes the Secretary to insure an individual mortgage on a one-family unit in a multifamily project and an undivided interest in the common areas and facilities that serve the project, provided certain conditions are met. The regulations at 24 CFR 234.26(b) provide that the project in which a unit is located shall be committed to a plan of condominium ownership by a deed or other recorded instrument that is acceptable to the FHA Commissioner. As it relates to condominiums, recordation especially commits the developer to following through with the establishment of a viable condominium. Recordation marks a specific point in time when various fees must be paid and when rights and obligations vest in a non-profit condominium association that has been created by the articles of condominium association.

Section 234(k) of the Act provides that, before FHA mortgage insurance can be placed on a unit in a condominium project converted from rental property, at least one year must elapse between the date of conversion and the date application for insurance is made. Conversion is not defined in the Act. HUD's regulations at 24 CFR 234.3 define conversion as the date on which all documents necessary to create a condominium under State law (and under local law) have been recorded.

Under the Commonwealth of Puerto Rico's inscription law, the legal documents to create a condominium regime are "presented" to the Commonwealth Office of the Property Registry, which closely reviews the documents for sufficiency and accuracy. If the documents are found to be in compliance, or can be corrected to be brought into compliance, the documents then are inscribed or recorded. (Because of a current backlog, the review process now takes several years.) When the condominium documents are presented, a condominium regime is established. During the review period, the purchaser acquires a fee interest in a unit together with a common, undivided interest in the common areas as do purchasers in those jurisdictions with more standard recordation procedures. Only in extraordinary circumstances would recordation of the condominium documents not ultimately occur once the legal documents are presented to the Commonwealth Office of the Property Registry.

From the time the condominium legal documents are presented for inscription,

the developer/proponent is responsible for paying assessments and costs associated with operating and maintaining the project as a condominium. This can result in substantial cost to a developer prior to the project's eligibility for FHA mortgage insurance.

II. This Rule

This proposed rule would revise the definition of "conversion" in 24 CFR 234.26(b) to provide that, in the case of Puerto Rico, conversion is defined as the date on which a condominium development's legal documents (which must be in compliance with applicable law) are "presented" for inscription (*i.e.*, recordation) to the Commonwealth Registry under Puerto Rico's inscription process. This revision would allow the Department's approval of condominium developments in Puerto Rico for FHA mortgage insurance on individual units within the project on the basis of evidence of presentation of legal documents and the parties obtaining title insurance on each unit.

III. Findings and Certifications

Environmental Review

A Finding of No Significant Impact with respect to the environment for this rule has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the office of the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street, SW., Washington, DC 20410.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This proposed rule does not impose a Federal mandate that will result in expenditure by State, local, or tribal governments, within the meaning of the Unfunded Mandates Reform Act of 1995.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule before publication and by approving it certifies that this rule would not have a significant economic impact on a substantial number of small entities. There are no anti-competitive

discriminatory aspects of the rule with regard to small entities, and there are no unusual procedures that would need to be complied with by small entities. Although HUD has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities, HUD welcomes comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule would not have federalism implications and would not

impose substantial direct compliance costs on State and local governments nor preempt State law within the meaning of the Executive Order.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance Numbers for 24 CFR part 234 are 14.117 and 14.133.

List of Subjects in 24 CFR Part 234

Condominiums, Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, HUD proposes to amend 24 CFR part 234 to read as follows:

PART 234—CONDOMINIUM OWNERSHIP MORTGAGE INSURANCE

1. The authority citation for 24 CFR part 234 continues to read as follows:

Authority: 12 U.S.C. 1715b and 1715y; 42 U.S.C. 3535(d).

2. The definition of "conversion" in § 234.3 is revised to read as follows:

§ 234.3 Definitions

* * * * *

Conversion means the date on which all documents necessary to create a condominium under State law (and under local law, where applicable) have been recorded, except that in the case of the Commonwealth of Puerto Rico, *conversion* is defined as the date on which the legal documents (which must be in compliance with applicable law) to create a condominium are presented for inscription (*i.e.*, recordation) to the Commonwealth Office of the Property Registry.

* * * * *

Dated: July 8, 2002.

John C. Weicher,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 02-21225 Filed 8-20-02; 8:45 am]

BILLING CODE 4210-27-P



Federal Register

**Wednesday,
August 21, 2002**

Part VI

Department of Transportation

Federal Aviation Administration

**14 CFR Parts 121, 125, and 135
Revisions to Digital Flight Data Recorder
Requirements; Final Rule**

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Parts 121, 125, and 135**

[Docket No.: FAA-2002-11705; Amendment No. 121-292, 125-39 and 135-85]

RIN 2120-AH81

Revisions to Digital Flight Data Recorder Requirements

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the flight data recorder regulations by expanding the recording ranges for certain data parameters for all covered airplanes. This amendment is necessary because certain airplanes are unable to record certain flight parameters under the existing resolution criteria without undergoing unintended and expensive retrofit.

DATES: This final rule is effective on August 20, 2002.

FOR FURTHER INFORMATION CONTACT: Gary Davis, Flight Standards Service, Air Transportation Division, AFS-201A, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267-8166; facsimile (202) 267-5229, e-mail gary.davis@faa.gov.

SUPPLEMENTARY INFORMATION:**Availability of Rulemaking Documents**

You can get an electronic copy using the Internet by taking the following steps:

- (1) Go to the search function of the Department of Transportation's electronic Docket Management System (DMS) web page (<http://dms.dot.gov/search>).
- (2) On the search page type in the last five digits of the Docket number shown at the beginning of this notice. Click on "search."
- (3) On the next page, which contains the Docket summary information for the Docket you selected, click on the document number for the item you wish to view.

You can also get an electronic copy using the Internet through the Office of Rulemaking's web page at <http://www.faa.gov/avr/armhome.htm> or the Government Printing Office's web page at http://www.access.gpo.gov/su_docs/aces/aces140.html.

You can also get a copy by submitting a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by

calling (202) 267-9680. Make sure to identify the amendment number or docket number of this rulemaking.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact their local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT**. You can find out more about SBREFA on the Internet at our site, <http://www.faa.gov/avr/arm/sbreffa.htm>. For more information on SBREFA, e-mail us 9-AWA-SBREFA@faa.gov.

Background

The regulations adopted by the FAA in August of 1997 (62 FR 38362) substantially improved the requirements for flight data recorders and mandated that up to 88 parameters of flight data of recorded for diagnostic use in the event of an accident or serious incident. Most of the improvements in the recording capacity did not directly affect Airbus airplanes, however, because almost all of the additional parameters required by the FAA had been incorporated previously into Airbus product specifications. In the case of a few parameters, however, Airbus airplanes were unable to meet the parameter recording requirements adopted in the rule. In 1997, the FAA stated that it had tailored the rule to avoid major equipment redesign or retrofits. The new requirements were to be met in stages, with the first 34 parameters being required at the next heavy maintenance check after August 18, 1999, but no later than August 20, 2001; followed by parameters 35 through 57 for aircraft manufactured after August 18, 2000, upon delivery; and finally parameters 58 through 88 for aircraft manufactured after August 19, 2002, upon delivery.

On August 24, 1999 (64 FR 46117), the FAA amended the digital flight data recorder (DFDR) resolution and sampling requirements for several parameters for Airbus airplanes. The amendments addressed only the first 34 parameters. Similarly, on August 24, 2000 (64 FR 51741), the FAA revised the DFDR regulations, making technical changes related to parameters 35 through 57 to accommodate Airbus airplanes.

Petition for Rulemaking

By letter dated February 22, 2002, Airbus petitioned the FAA to further amend Appendix M to part 121 and Appendix E to part 125. The letter states that Airbus had completed its audit of compliance requirements for parameters 58 through 88, and identified three specific technical issues of compliance for which it sought relief. Specifically, Airbus seeks minor technical changes to the recording requirements for parameter 83 (cockpit trim control input position—roll), parameter 84 (cockpit trim control input position—yaw), and parameter 88 (cockpit flight control input force—rudder). However, since its February letter, Airbus has withdrawn its request for changes to the requirements for parameter 88.

Airbus notes that the FAA, in adopting the new DFDR recording resolution requirements, did not intend to require equipment redesign or retrofit, and that the requested specification changes would be consistent with that intent. Airbus airplanes have been recording these parameters for many years, and Airbus claims that there would be no safety or analytic benefit to replace sensors that are virtually compliant with the regulatory specifications. According to Airbus, the deviations to current resolution requirements they are seeking are small, and are consistent with the smallest increment employed in the parameters for actual measurement of the respective flight control surfaces.

Specifically, Airbus seeks changes to the DFDR recording requirements for the following parameters as contained in Appendix M to part 121 and appendix E to part 125 of 14 CFR:

Parameter 83, cockpit trim control input position—roll, is required to be resolved to 0.028 degrees (0.2% of operational range of ± 7 degrees). On A310 and A300-600 series aircraft this is implemented with a resolution of 0.096 degrees. Airbus asserts that this resolution is nearly identical to the smallest increment used in deflection of the roll control surfaces for each model, which is 0.092 degrees in the A310 aircraft and 0.091 degrees in the A300-600 aircraft. Airbus states that achieving the additional resolution would provide no substantive benefit. Airbus requests that a footnote be added in Appendix M to part 121 and Appendix E to part 125, to reflect this deviation for the airplane models noted.

Parameter 84, cockpit trim control input position—yaw, is required to be resolved to 0.08 degrees (0.2% of operational range of ± 20 degrees). On A318/319/320/321 series aircraft, this is

implemented with a resolution of 0.088 degrees. Airbus asserts that this resolution surpasses the smallest increment used to deflect the yaw control surfaces for each model, which is 0.112 degrees for the A320 family. Airbus requests that a footnote be added in Appendix M to part 121 and Appendix E to part 125, to reflect this deviation for the airplane models noted.

Airbus states that U.S. operators of the affected airplanes would incur substantial costs associated with being involved in the redesign and installation of new DFDR equipment to achieve precise compliance with the recording resolution requirements of the current regulations. In addition, if new aircraft were delivered with DFDR recording equipment that differs from that installed on existing aircraft, operators would have to maintain the equipment separately, increasing recordkeeping requirements and costs. Airbus states that these added costs would not be balanced by any increase in safety or investigative capability. Accordingly, Airbus concludes that it is in the public interest to make the requested regulatory modifications.

Discussion of Comments

On April 22, 2002, the FAA published a notice of petition for rulemaking, with a request for comments, discussing this Airbus request (67 FR 19534). The comment period for that notice (Notice No. PE-2002-28) closed on May 22, 2002. In response to that notice we received two generally favorable comments, one from the Air Transport Association (ATA) and another from the Boeing Airplane Company (Boeing). The ATA supports the Airbus petition, reaffirming that the 1997 rule was not intended to necessitate retrofit modifications. The ATA agrees with the petitioner's claim that the required changes to the production configurations and the resulting differences with the configurations for airplanes already in service would be neither cost effective nor beneficial in mishap investigations.

Boeing concurs with the requested revisions to the parameter 83 and parameter 84 resolutions, stating that they are minor and would not significantly affect the ability of accident investigators to perform their investigation. However, Boeing questioned the need to revise the accuracy requirement for parameter 88, and is concerned that any changes to the rule might affect the method of compliance for which it had received approval. Since Airbus withdrew its request to amend the recording requirements of parameter 88, no

change to that parameter is included in this amendment.

FAA's Response

The FAA considered carefully all the comments received. Because no commenter opposed the requested changes to parameters 83 and 84, the FAA has determined that the changes would be in the public interest.

Airbus requested that these amendments be codified as footnotes to the affected appendixes. After considerable discussion with technical representatives and accident investigators, however, the FAA has determined the requested changes can be made to the appendixes and made available to all airplanes without compromising resources available to accident investigators. The incremental difference in the measurements obtained are considered insignificant. Further, the FAA notes that the same parameters and resolution requirements appear in Appendix F to part 135. Because the changes requested will apply to all airplanes subject to parts 121 and 125, the FAA finds that the same changes are appropriate for the part 135 requirements. Accordingly, in Part 121 Appendix M, Part 125 Appendix E, and Part 135 Appendix F, resolution recording requirements for parameters 83 and 84 will be amended to read 0.7% and 0.3% of full range, respectively.

Good Cause for Immediate Adoption

Sections 553(b)(3)(B) and 553(d)(3) of the Administrative Procedure Act (APA) (5 U.S.C. Sections 553(b)(3)(B) and 553(d)(3)) authorize agencies to dispense with certain notice procedures for rules when they find "good cause" to do so. Under section 553(b)(3)(B), the requirements of notice and opportunity for comment do not apply when the agency, for good cause, finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Section 553(d)(3) allows an agency, upon finding good cause, to make a rule effective immediately, thereby avoiding the 30-day delayed effective date requirement in section 553.

The FAA finds that the requirements for notice and public comment to this amendment have been met because the FAA published for comment Airbus's original petition for rulemaking. Further, if the changes are delayed awaiting additional public notice and comment, regulated entities would be unable to comply with an August 20, 2002, compliance deadline. Therefore, the FAA finds that further notice and comment are unnecessary and that good

cause exists for making these amendment effective on August 20, 2002.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has determined that there are no new requirements for information collection associated with this rule.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Economic Evaluation, Regulatory Flexibility Determination, Trade Impact Assessment, and Unfunded Mandates Assessment

Proposed changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs each Federal agency to propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. section 2531-2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act also requires agencies to consider international standards and, where appropriate, use them as the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation.)

Regulations with an expected minimal impact the above-specified analyses are not required. The Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If it is determined that the expected impact is so minimal that the proposal does not warrant a full Evaluation, a statement to

that effect and the basis for it is included in the proposed regulation. The FAA has determined that there are no costs associated with this final rule. Instead, this rule change relieves operators of Airbus airplanes from a cost that would have been inadvertently imposed on them in the adoption of the 1997 regulations. This cost would have been imposed beginning on August 20, 2002. This change effectuates the original intent of the 1997 regulations.

In conducting these analyses, FAA has determined this rule (1) has benefits which justify its costs; (2) is not a "significant regulatory action" as defined in section 3(f) of Executive Order 12866 and is not "significant" as defined in DOT's Regulatory Policies and Procedures; (3) will not have a significant impact on a substantial number of small entities; (4) will have little effect on international trade; and (5) does not impose an unfunded mandate on state, local, or tribal governments, or on the private sector.

The purpose of this rule is to eliminate the necessity to incorporate unnecessary changes into an existing type of airplane that already meets the requirements of the rule except for minor variations in the resolution recording requirement. The FAA has determined that allowing the continued resolution-recording at a slightly different value will not impact safety or the collection of accident investigation data. This rule would result in cost savings because air carriers would not have to make minor, but costly, changes and subsequently pass those costs on to the public in the form of higher ticket prices.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation." To achieve that principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as

described in the Act. However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 Act provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule will relieve unnecessary costs to operators of certain airplanes. Therefore, the FAA expects this rule to impose no cost on small entities. Consequently, the FAA certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this rulemaking and has determined that it will reduce costs to U.S. operators of certain airplanes but will have a minimal effect on international trade.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act), enacted as Public Law 104-4 on March 22, 1995, is intended, among other things, to curb the practice of imposing unfunded Federal Mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a \$100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action."

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Executive Order 3132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. We determined that this action will not

have a substantial direct effect on the States, or the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, we determined that this final rule does not have federalism implications.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental impact statement. In accordance with FAA order 1050.1D, appendix 4, paragraph 4(j), this rulemaking action qualifies for a categorical exclusion.

Energy Impact

The energy impact of the notice has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) Public Law 94-163, as amended (42 U.S.C. 6362) and FAA Order 1053.1. It has been determined that the final rule is not a major regulatory action under the provisions of the EPCA.

List of Subjects

14 CFR Part 121

Air carriers, Aircraft, Aviation safety, Reporting and recordkeeping requirements, Safety, Transportation.

14 CFR Part 125

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 135

Air taxis, Aircraft, Airmen, Alcohol abuse, Aviation safety, Drug abuse, Drug testing, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends Chapter 1 of Title 14, Code of Federal Regulations as follows:

PART 121—OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

1. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 40119, 41706, 44101, 44701-44702, 44705, 44709-44711, 44713, 44716-44717, 44722, 44901, 44903-44904, 44912, 45101-45105, 46105, Pub. L. 107-71, 115 Stat. 597-647.

2. Amend Appendix M to part 121 to revise numbers 83 and 84 to read as follows:

Appendix M to Part 121—Airplane Flight Recorder Specifications

The recorded values must meet the designated range, resolution, and

accuracy requirements during dynamic and static conditions. All data recorded must be correlated in time to within one second.

Parameters	Range	Accuracy (sensor input)	Seconds per sampling interval	Resolution	Remarks
83. Cockpit trim control input position—roll.	Full Range	±5%	1	0.7% of full range.	Where mechanical means for control inputs are not available, cockpit display trim position should be recorded.
84. Cockpit trim control input position—yaw.	Full range	±5%	1	0.3% of full range.	Where mechanical means for control input are not available, cockpit display trim positions should be recorded.

* * * * *

PART 125—CERTIFICATION AND OPERATIONS: AIRPLANES HAVING A SEATING CAPACITY OF 20 OR MORE PASSENGERS OR A MAXIMUM PAYLOAD CAPACITY OF 6,000 POUNDS OR MORE; AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

3. The authority citation for part 125 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44705, 44710–44711, 44713, 44716–44717, 44722.

4. Amend Appendix E to part 125 to revise item numbers 83 and 84 to read as follows:

Appendix E to Part 125—Airplane Flight Recorder Specifications

The recorded values must meet the designated range, resolution, and accuracy requirements during dynamic

and static conditions. All data recorded must be correlated in time to within one second.

Parameters	Range	Accuracy (sensor input)	Seconds per sampling interval	Resolution	Remarks
83. Cockpit trim control input position—roll.	Full Range	±5%	1	0.7% of full range.	Where mechanical means for control inputs are not available, cockpit display trim position should be recorded.
84. Cockpit trim control input position—yaw.	Full Range	±5%	1	0.3% of full range.	Where mechanical means for control input are not available, cockpit display trim positions should be recorded.

* * * * *

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

5. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 41706, 44113, 44701–44702, 44709, 44705, 44711–44713, 44715–44717, 44722.

6. Amend Appendix F to part 135 revise item numbers 83 and 84 to read as follows:

Appendix F to Part 135—Airplane Flight Recorder Specifications

The recorded values must meet the designated range, resolution, and accuracy requirements during dynamic and static conditions. All data recorded must be correlated in time to within one second.

Parameters	Range	Accuracy (Sensor input)	Seconds per sampling interval	Resolution	Remarks
83. Cockpit trim control input position—roll.	Full Range	±5%	1	0.7% of full range.	Where mechanical means for control inputs are not available, cockpit display trim position should be recorded.

Parameters	Range	Accuracy (Sensor input)	Seconds per sam- pling inter- val	Resolution	Remarks
84. Cockpit trim control input posi- tion—yaw.	Full Range	±5%	1	0.3% of full range.	Where mechanical means for control input are not available, cockpit display trim positions should be recorded.

* * * * *

Issued in Washington, DC, on August 15,
2002.
Monte R. Belger,
Acting Administrator.
[FR Doc. 02–21171 Filed 8–19–02; 9:44 pm]
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LIST OF PUBLIC LAWS

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H.R. 3009/P.L. 107-210

Trade Act of 2002 (Aug. 6, 2002; 116 Stat. 933)

Last List August 9, 2002

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